

# **EXHIBIT D**

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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

- - - - - x  
IN RE: VALSARTAN, LOSARTAN, AND : MDL NO. 2875  
IRBESARTAN PRODUCTS LIABILITY :  
LITIGATION, :  
:  
THIS DOCUMENT RELATES TO: :  
Duffy, et al. v. Solco Healthcare :  
U.S., L.L.C., et al., :  
Case No. 1:18-cv-15076-RBK-JS :  
- - - - - x

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Veritext Virtual Zoom Videotaped  
deposition of MAHYAR ETMINAN, Ph.D., taken on  
Tuesday, August 24, 2021, held in Vancouver, City of  
British Columbia, Canada, commencing at 8:00 a.m.,  
before Jamie I. Moskowitz, a Certified Court  
Reporter and Certified Livenote Reporter.

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1 REQUEST PAGE

2 INSTRUCTIONS NOT TO ANSWER:

3 Page Line

4 None

5 REQUEST FOR PRODUCTION OF DOCUMENTS:

6 Page Line Description

7 None

8 STIPULATIONS:

9 Page Line

10 None

11 QUESTIONS MARKED:

12 Page Line

13 None

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1 THE VIDEOGRAPHER: We are going on the  
2 record at 8 a.m. on August 24th, 2021. This is  
3 Media Unit Number 1 of the video recorded  
4 deposition of Mahyar Etminan in regards to the  
5 valsartan, losartan litigation.

6 My name's Justin Bily from the firm  
7 Veritext and I am the videographer. The court  
8 reporter is Jamie Moskowitz from the firm  
9 Veritext. All counsel will be noted on the  
10 stenographic record. Will the court reporter  
11 please swear in witness and then we can begin.

12 \* \* \*

13 P R O C E E D I N G S

14 THE COURT REPORTER: The attorneys  
15 participating in this deposition acknowledge  
16 that I am not physically present in the  
17 deposition room and that I will be reporting  
18 this deposition remotely.

19 They further acknowledge that, in lieu  
20 of an oath administered in person, the witness  
21 will verbally declare his testimony in this  
22 matter is under penalty of perjury.

23 The parties and their counsel consent  
24 to this arrangement and waive any objections to  
25 this manner of reporting. If there are any

1 objections, please state them now.

2 \* \* \*

3 MAHYAR ETMINAN, after having been  
4 first duly sworn, was examined and testified as  
5 follows:

6 \* \* \*

7 THE COURT REPORTER: Okay, please  
8 proceed.

9 EXAMINATION BY MR. GALLAGHER:

10 Q Good morning, Dr. Etminan. You can  
11 put your hand down now.

12 A Good morning.

13 Q My name is Patrick Gallagher. I'm  
14 with the law firm of Duane Morris. I represent some  
15 of the defendants in this matter, and I'll be asking  
16 you a series of questions today for your deposition.  
17 Can you please state your name for the record?

18 A Mahyar Etminan.

19 Q Dr. Etminan, have you ever been  
20 deposed before?

21 A Yes.

22 Q How many times?

23 A Just off the top of my head, at least  
24 four or five times.

25 Q Okay. When did you first speak with

1 plaintiffs' counsel with respect to this case?

2 A Again, to the best of my recollection,  
3 I believe it was probably in late spring, maybe  
4 April or May.

5 Q Okay. And who was that counsel that  
6 you first spoke to about this case?

7 A Again, it was either Mr. Nigh or  
8 Ms. -- I forget her last name. Rosemarie.

9 Q Okay.

10 A I don't -- I'm not sure exactly which  
11 one posed the question, but they both approached me.

12 Q Okay. And have you ever spoken to  
13 either -- either Mr. Nigh or Rosemarie prior to  
14 speaking to them about this case?

15 A I did some work for them on a  
16 different litigation as well.

17 Q Did you serve as a testifying expert?

18 MR. NIGH: Hold on. Don't answer that  
19 question. We have not disclosed experts in  
20 Zantac, so I'm not going to allow him to answer  
21 any more questions about the Zantac litigation.

22 MR. GALLAGHER: Okay.

23 BY MR. GALLAGHER:

24 Q Other than this case, have you had  
25 other -- strike that.

1 Have you spoken to any other experts  
2 involved in this case, the valsartan litigation?

3 A No.

4 Q Okay. Have you reviewed any -- have  
5 you reviewed any expert reports of other experts  
6 with respect to this litigation?

7 A Yes, I have reviewed Dr. Prizing, I  
8 believe, and their reports.

9 Q Okay.

10 MR. GALLAGHER: Can we mark the first  
11 exhibit Exhibit 1? It's the deposition notice.

12 (Whereupon, Exhibit 1 was marked for  
13 Identification.)

14 MS. APPEL: It's already marked.

15 BY MR. GALLAGHER:

16 Q Dr. Etminan, have you seen this  
17 document before?

18 A Yes.

19 MR. GALLAGHER: And if we go to the --  
20 I think it's on the next page, next page.

21 BY MR. GALLAGHER:

22 Q Have you -- did you review this?

23 MR. GALLAGHER: Then we can skip ahead  
24 to the next page.

25 THE WITNESS: Yes, I have.

1 BY MR. GALLAGHER:

2 Q Do you see there's a series of  
3 requests for certain documents? Did you -- did you  
4 collect documents to -- to be produced in response  
5 to these requests?

6 A Yes.

7 MR. NIGH: And for the record, we did  
8 serve response to his requests on defense  
9 counsel more than 48 hours prior to this  
10 deposition.

11 MR. GALLAGHER: We did receive --  
12 receive those documents.

13 BY MR. GALLAGHER:

14 Q How did you go about collecting the  
15 documents that you provided in response to these  
16 requests?

17 A I provided all documents, pertinent  
18 studies that I used to formulate an opinion in my  
19 expert report, including my search strategy and,  
20 again, the articles that I found that sort of  
21 contributed to the weight of the evidence that I  
22 used in my report.

23 Q Okay. And with respect to the  
24 articles that you provided in response to the  
25 request, how did you -- how did you decide what

1 articles you were going include and provide?

2 A Again, the articles where I talked  
3 about extensively in the report, that contribute  
4 substantially to the weight of the evidence, I have  
5 included all of those articles.

6 Q Okay. Did you have like a file of  
7 these articles, or was -- were you --

8 A Well, I had --

9 MR. NIGH: Form. Objection.

10 THE WITNESS: I -- I -- my report is  
11 mainly a systematic review of the literature.  
12 So when I did my systematic review, I found  
13 articles that met the selection criteria in  
14 that review. So I went ahead and completed the  
15 report. And when I received this request, I  
16 went back and looked at all the -- the main  
17 articles or studies that I have included. And  
18 I went about selecting them again, using mainly  
19 the criteria in my research, in my search and  
20 also the weight of the evidence that they  
21 contributed to the report.

22 BY MR. GALLAGHER:

23 Q So I think that -- the documents  
24 that -- or the articles -- strike that.

25 The articles that you provided in



1 response to these requests, include some of the  
2 articles and papers that are cited in your report  
3 but not all of the articles and papers that are  
4 cited in your report.

5 MR. NIGH: Hold on, Doctor. Doctor,  
6 hold on. Hold on. If you can, let Patrick  
7 finish his question. I know it may be a little  
8 difficult because it sometimes does sound like  
9 he trails off at the end. But at the same  
10 point, I need a pause in between his question  
11 and your answer, so I that I can, you know,  
12 interject an objection if I -- if I need to.

13 So here, I'm going to object to form.  
14 Go ahead, you can answer, Doctor.

15 THE WITNESS: Yeah, so if there were  
16 citations in the report where I only looked at  
17 the abstract of the paper and not really  
18 included the body of the paper because I didn't  
19 need to, those articles are just cited in my  
20 report. But I provided the articles that  
21 actually contributed to the weight of the  
22 evidence and my opinions in the report.

23 BY MR. GALLAGHER:

24 Q So would it be fair to say, then, that  
25 articles that are cited -- that may be cited in your

1 report but that you did not provide in response to  
2 these requests did not contribute to your opinions  
3 in this matter?

4 MR. NIGH: Form. Objection.

5 Misstates his testimony.

6 You can answer.

7 THE WITNESS: No, they do. Again,  
8 if -- if there was -- if there were statements  
9 that I made that are general statements that  
10 are -- that are sort of known facts, I, you  
11 know, didn't really provide those specific  
12 articles. But I cite them. I provided  
13 articles where I, you know, make a lot of  
14 discussions around the weight of the evidence  
15 provided in those articles.

16 BY MR. GALLAGHER:

17 Q Okay. Let's move on and mark as  
18 Exhibit 2 your CV.

19 (Whereupon, Exhibit 2 was marked for  
20 Identification.)

21 THE WITNESS: Sorry. Is this going to  
22 be a document upload or is it --

23 BY MR. GALLAGHER:

24 Q It is.

25 A I'm still waiting.

1 MR. NIGH: Yeah, we don't have it yet.

2 There it is. Do you have it, Doctor?

3 THE WITNESS: I got it, yeah.

4 BY MR. GALLAGHER:

5 Q So Dr. Etminan, you're an associate  
6 professor in the Department of Ophthalmology and  
7 Visual Sciences; is that correct?

8 A That's right.

9 Q At the University of British Columbia,  
10 correct?

11 A Correct.

12 Q What does that position entail?

13 A The position is mainly 60, 70 percent  
14 research position. And the 30 or 40 percent  
15 remainder is basically -- basically, it's made up of  
16 teaching, graduate and undergraduate training and a  
17 few hours a month of service.

18 Q And when you refer to service, what do  
19 you mean by "service"?

20 A Service means attending committees,  
21 departmental meetings, that sort of thing.

22 Q Okay. And in your teaching, what  
23 courses do you teach?

24 A Currently, I teach a two-hour course  
25 on evidence-based medicine and with a -- with a

1 focus on causal inference to pharmacy students. I  
2 also teach a similar lecture to graduate students in  
3 the department of ophthalmology. And another  
4 pharmacy course on evidence-based medicine, with --  
5 one is undergraduate, and one is for the pharmacy  
6 residents who have graduated. But it's two  
7 different courses but same sort of topic:  
8 evidence-based medicine.

9 Q Okay. And I believe you mentioned in  
10 the 30 to 40 percent, you said teaching and  
11 graduate, undergraduate training. Is there any  
12 aspect of graduate or undergraduate training you're  
13 referring to other than the courses you teach?

14 A Right. So I teach undergraduate  
15 medical students, and it's more of a -- sort of a  
16 research rotation, if you will, that they have. So  
17 they spend six to eight weeks reading up on  
18 epidemiological methodology and taking on a project.  
19 I do some -- the same sort of research teaching as  
20 well to ophthalmology residents.

21 And then I have also graduate students  
22 who are enrolled in a master's or a Ph.D. program  
23 through the Department of Experimental Medicine, and  
24 I supervise them on sort of a more regular basis  
25 because they're -- you know, they're graduate

1 students working toward a master's or a Ph.D.

2 THE COURT REPORTER: I'm sorry.

3 You -- they have a master's or Ph.D. through  
4 the Department of Experimental Medicine? I'm  
5 sorry, I missed what you said.

6 THE WITNESS: Yes, so experimental  
7 medicine is a department where all faculties of  
8 school -- all faculties who are researching in  
9 the faculty of medicine can train students  
10 through the Department of Experimental  
11 Medicine. So it's like an academic hub, if you  
12 will, to -- for graduates training in the -- in  
13 the faculty of medicine.

14 MR. NIGH: And, Doctor, if Jamie  
15 speaks up -- or Ms. Moskowitz, if she speaks  
16 up, she just wants to clarify what words you  
17 used at the end of a sentence. Patrick is  
18 going to be the one asking you questions about  
19 like what is that type of thing. Okay?

20 THE WITNESS: Okay.

21 BY MR. GALLAGHER:

22 Q Dr. Etminan, in the -- you referred to  
23 graduate and undergraduate students. Do you teach  
24 medical students?

25 A Yes, I teach undergraduate medical

1 students. I also have started teaching, as I  
2 mentioned to you, undergraduate pharmacy students as  
3 well.

4 Q How long have you been a professor at  
5 the University of British Columbia?

6 A Since 2008.

7 Q And where were you immediately before  
8 you started at the University of British Columbia?

9 A Before -- I held a research associate  
10 position at Vancouver General Hospital. Before I  
11 was, you know, I started my professorial position, I  
12 worked as a research associate for 2 or 3 years at  
13 Vancouver Hospital.

14 Q Okay. And, Dr. Etminan, you received  
15 a PharmD degree from Idaho State University; is that  
16 correct?

17 A That's right.

18 Q Did you do your -- did you attend any  
19 other universities for a PharmD program?

20 MR. NIGH: Form objection.

21 THE WITNESS: Yes, I -- I started my  
22 PharmD at the University of British Columbia,  
23 but I completed it at Idaho State University.

24 BY MR. GALLAGHER:

25 Q And so how many years did you -- what

1 year did you start the PharmD program at the  
2 University of British Columbia?

3 A I believe it was in 1999, or actually  
4 1998 or 9, I forget. And I did one year at UBC, and  
5 then I transferred and completed my degree at Idaho.

6 Q Okay. Why did you transfer?

7 A I felt that the program, it does not  
8 really state my, sort of, objectives, which were  
9 more research, pharmaceutical research in  
10 epidemiology. It was a more of a clinical program,  
11 so I completed it -- Idaho allowed me to finish my  
12 degree faster and then go ahead and continue my  
13 training in epidemiology.

14 Q Okay. And then after your PharmD, you  
15 went to the University of Toronto; is that correct?

16 A That's right.

17 Q And what was the program you were  
18 enrolled in at University of Toronto?

19 A It was a master's degree in clinical  
20 epidemiology.

21 Q Then looks like subsequently, you did  
22 a postdoctoral fellowship at McGill University; is  
23 that correct?

24 A That's right.

25 Q What was the nature of your work

1 during that postdoctoral fellowship?

2 A I undertook epidemiological studies on  
3 prescription drugs, safety questions using launch  
4 databases or big data.

5 Q Did any of those studies involve the  
6 study of cancer?

7 A No, not -- not during my training at  
8 McGill. I wasn't -- no. Or at least I don't  
9 remember. I have done a lot of studies. I don't  
10 think one of my studies at McGill had anything to do  
11 with cancer.

12 Q Okay. Jumping ahead to -- as we  
13 discussed just a few minutes ago, you're a professor  
14 in the Department of Ophthalmology and Visual  
15 Sciences, correct?

16 A That's right.

17 Q And I think you said 60 to 70 percent  
18 of your time was -- was research?

19 A That's right.

20 Q What's the primary -- what's the  
21 primary focus of your research currently?

22 A My primary focus of my research again  
23 is sort of broken down to 40 to 50 percent  
24 epidemiology of the eye or ocular diseases or drug  
25 safety questions related to the eye. And the rest



1 of the -- the other 40 to 50 percent is drug safety  
2 questions on any other area in -- in medicine. So I  
3 worked on drugs related to the lung, to the  
4 gastrointestinal tract, any -- anything -- any drug  
5 safety question that is of public health concern.

6 Q How do you identify drugs that you're  
7 going to undertake research on?

8 MR. NIGH: Form objection.

9 THE WITNESS: Well, it's usually case  
10 reports or case series or alerts from drug  
11 regulatory agencies. Sometimes the media is a  
12 good source to highlight important --  
13 importance of a safety question. So it could  
14 be a combination of all of those, or it could  
15 be one of them.

16 BY MR. GALLAGHER:

17 Q You're not a medical doctor, correct?

18 A No.

19 Q And you don't diagnose patients,  
20 correct?

21 A No.

22 Q You don't treat patients, correct?

23 A Correct.

24 Q When I asked you about what you did as  
25 a professor in the Department of Ophthalmology and

1 Visual Science, you didn't mention anything about  
2 clinical involvement. That's not a part of what you  
3 do as a professor at the  
4 University of British Columbia, correct?

5 A Correct.

6 Q I believe you said you -- I believe  
7 you have been deposed four or five times; is that  
8 correct?

9 A Correct.

10 Q Have you ever testified at trial?

11 A I testified, I believe, in the lower  
12 Manhattan court for Fosamax once, yes.

13 Q Okay. Do you know if your testimony  
14 has ever been excluded by a court?

15 MR. NIGH: Form objection.

16 THE WITNESS: I'm not sure. It's  
17 possible -- possibly Fosamax, but I'm not  
18 100 percent sure.

19 Q Okay.

20 THE COURT REPORTER: I'm sorry. What  
21 was that? Fosamax?

22 THE WITNESS: Right. Fosamax.

23 F-o-s-a-m-a-x.

24 THE COURT REPORTER: Oh, Fosamax.

25 Okay. Thank you.

1 BY MR. GALLAGHER:

2 Q Dr. Etminan, have you ever withdrawn  
3 as an expert in this case?

4 MR. NIGH: Form objection.

5 THE WITNESS: Yes.

6 THE COURT REPORTER: I'm sorry .I need  
7 the question repeated.

8 BY MR. GALLAGHER:

9 Q Dr. Etminan, have you ever withdrawn  
10 as an expert in a case?

11 MR. NIGH: Form objection.

12 THE WITNESS: Yes.

13 BY MR. GALLAGHER:

14 Q What case did you withdraw as an  
15 expert?

16 A It was the Mirena litigation.

17 Q Why did you withdraw?

18 A I felt that I could not contribute  
19 anymore to the litigation, and I felt more  
20 comfortable to withdraw.

21 Q Dr. Etminan, do you consider yourself  
22 to be a statistician?

23 A I'm not a statistician, but I have  
24 good familiarity with biostatistics that pertains to  
25 my line of work in the area of epidemiology that

1 I -- that I work at.

2 Q Would you say that you use statistics  
3 in your work as an -- as an epidemiologist?

4 A Yes.

5 Q Okay. What does the term  
6 "statistically significant" mean --

7 THE COURT REPORTER: I'm sorry.

8 There's -- there's background noise coming in.  
9 I'm not sure where it's coming from, but I'm  
10 not hearing you well.

11 MR. GALLAGHER: I'll -- I'll repeat  
12 the question.

13 BY MR. GALLAGHER:

14 Q What does the term "statistically  
15 significant" mean from an epidemiological  
16 standpoint?

17 A Actually, it's -- that's a great  
18 question. So for many, believe that the  
19 statistically significant means that results of a  
20 study are -- for example, if the P value is large  
21 and the results are not statistically significant,  
22 that means that the -- there is really no effect  
23 associated with that -- that exposure, carcinogen.

24 But in reality, this is really not the  
25 case. And the American Statistical Association, in

1 2016, published commentary to sort of clear the  
2 water on this issue.

3 So the correct interpretation of your  
4 question on statistical significance means that if  
5 some -- if an effect size of a -- from a study is  
6 not statistically significant, that means that it  
7 does not deviate from the statistical model and  
8 assumptions that it -- that it carries with it.

9 It does not have anything -- it does  
10 not say anything at all about whether, you know,  
11 that particular exposure of a study and the outcome  
12 are related or associated. That's -- that's all it  
13 means, that the -- the data and the assumptions  
14 around that data for that analysis do not deviate.

15 Q So what does that mean, to say that  
16 "the data and the assumptions do not deviate"?

17 MR. NIGH: Form objection.

18 THE WITNESS: Again, in more simple  
19 terms, when we do a study, there are -- the  
20 data that we use. The type of a statistical  
21 model that we use carries with it a number of  
22 assumptions.

23 And if -- if the results are  
24 statistically significant, all it means is that  
25 your data, the data that you have from that

1 study, are, if you will, different than --  
2 than -- than the model that you're using,  
3 provided that all other assumptions are met.

4 So it's more about whether the data  
5 fits in the assumptions or not. It's not  
6 about -- statistically significant means that,  
7 yes, this exposure causes this outcome, or if  
8 it's not significant, it means it doesn't.  
9 That's not what a statistical significant means  
10 at all.

11 BY MR. GALLAGHER:

12 Q So statistical significance -- are you  
13 saying -- what I understand you to be saying is that  
14 statistical significance is not evidence of  
15 causation?

16 MR. NIGH: Object to form,  
17 mischaracterizes his testimony.

18 THE WITNESS: Yeah, it's --  
19 statistical significance doesn't have anything  
20 to do with causation. Statistical  
21 significance, again, means how similar is my  
22 data to the statistical model that I'm using  
23 provided all other -- all the assumptions that  
24 need to be met are met. Sometimes they are  
25 not. But do the assumptions have to -- to be

1 met, so, again, there are caveats.

2 It also -- statistical significance  
3 also is a reflection of precision as well.  
4 Studies with a large sample size are -- are  
5 more precise in terms of the -- let's say, the  
6 confidence interval around the effect size  
7 because there are very large sample sizes.  
8 Usually, they have higher events.

9 Smaller studies with lower sample size  
10 and lower events usually have a wider  
11 confidence interval or a larger P value because  
12 of -- they're -- they're more imprecise. So,  
13 again, statistical significance and whether an  
14 exposure is causing an outcome are different --  
15 are two different entities.

16 BY MR. GALLAGHER:

17 Q In your work, do you have an  
18 understanding of the concept of adjusted rate ratio?

19 A Yes.

20 Q From your perspective, what is an  
21 adjusted rate ratio?

22 A An adjusted rate ratio is a rate  
23 ratios that's been adjusted using statistical  
24 modeling for either one other variable, which we  
25 call covariate. So it could be age, or it could be

1 adjusted for multiple variables.

2 Q And what's the purpose of doing the  
3 adjustment?

4 A The purpose of an adjustment is to  
5 make sure that the two groups exposed -- or, say,  
6 the drug group and the unexposed group are balanced  
7 with respect to potential confounding variables  
8 in -- in a particular study.

9 However, again, all of these issues  
10 have intricacies and nuances. And one of the  
11 nuances is that, you know, adjustment for the wrong  
12 variable can actually be detrimental as well. So we  
13 want to make sure that we adjust for variables that  
14 need to be adjusted for.

15 Q How do you determine what variables  
16 need to be adjusted for?

17 A Well, that's an area that actually I  
18 have been working on for the past few years, and I  
19 have been advocating. So what one of the -- sort of  
20 up-and-coming methods is the use of what we call  
21 "causal diagrams" where we draw -- draw out all the  
22 common causes of whatever the question is, whether  
23 it -- exposure on health that you're looking at. We  
24 draw all the common causes for that question, and  
25 then we find which -- which are the paths -- what we



1 call "biasing paths" that need to be adjusted for or  
2 blocked.

3 MR. GALLAGHER: Let's mark as the next  
4 exhibit, Exhibit 3, a paper in which you are an  
5 author, you cited in your report titled  
6 "Personal Use of Hair Dyes" --

7 THE COURT REPORTER: I'm sorry,  
8 "Personal Use of Hair Dye" --

9 MR. GALLAGHER: "And Risk of Cancer."  
10 (Whereupon, Exhibit 3 was marked for  
11 Identification.)

12 MR. GALLAGHER: That will be coming up  
13 shortly.

14 BY MR. GALLAGHER:

15 Q Do you have it, Dr. Etminan?

16 A Is that Exhibit 3?

17 Q Yes.

18 A Yes, I'm just opening it.

19 Q You're familiar with this paper?

20 A It's -- it's been a while because it  
21 was published a few years back, but yes.

22 Q Okay. When is the last time you read  
23 this paper?

24 A Many years ago.

25 Q Okay. It was published in 2005. That

1 would probably be the last time you read it?

2 A Yes.

3 Q What was your contribution to this  
4 paper?

5 A Again, as the best of my recollection,  
6 I helped with the search -- searching of the studies  
7 and the write of the manuscript -- write-up of the  
8 manuscript, yeah. So I think mostly gathering the  
9 evidence and writing the paper up.

10 Q Would you consider this to be a  
11 landmark paper?

12 MR. NIGH: Form objection.

13 THE WITNESS: It was -- I'm not sure  
14 what you mean by "landmark," but it was, at  
15 that time, the first study or review,  
16 comprehensive review of the topic.

17 BY MR. GALLAGHER:

18 Q If we go to Page 2519, which I think  
19 is the fourth page of the document, do you see  
20 there's a section here called "Quality Assessment"?

21 A Yes.

22 Q What was the purpose of doing a  
23 quality assessment?

24 THE COURT REPORTER: I'm sorry.

25 Doctor, can you start that again, please?

1 BY MR. GALLAGHER:

2 Q What was the purpose of doing a  
3 quality assessment?

4 A The purpose of a quality assessment  
5 was to look at the quality of the studies that was  
6 included.

7 Q And it looks like you tried to  
8 establish an objective 10-point scale to evaluate  
9 the quality of the study; is that correct?

10 A Let me just read it for a second.

11 Q Sure.

12 A So it seems like from the description  
13 that we came up with our own sort of a description  
14 of a quality assessment. It's nothing that is -- is  
15 validated. We kind of improvised based on this --  
16 you know, the type of data that we had.

17 Q Okay. But you established specific  
18 criteria by which the quality of the -- each of the  
19 studies that were included was evaluated?

20 A Yes.

21 Q Is that correct?

22 MR. NIGH: Object to the form.

23 THE WITNESS: Yeah.

24 BY MR. GALLAGHER:

25 Q If we go to Page 2523 of the article,

1 under -- do you see there's a heading "Comment," the  
2 paragraph right under that.

3 So it looks like the -- in this --  
4 this paper your -- the results indicated that  
5 there's no effect of personal hair dye use on the  
6 risk of breast and bladder cancer; is that correct?

7 A Yes.

8 Q And you concluded, there's a  
9 borderline effect for hematopoietic cancers, but the  
10 evidence of a causal effect is too weak to represent  
11 a major public health concern.

12 How did you --

13 MR. NIGH: We couldn't hear you. It  
14 just broke up during your question, Patrick.

15 THE WITNESS: Sorry. Patrick, can you  
16 repeat your question? I'm okay.

17 MR. GALLAGHER: Yes, I will repeat the  
18 question.

19 BY MR. GALLAGHER:

20 Q How did you decide that the causal  
21 effect is too weak?

22 MR. NIGH: Form objection.

23 THE WITNESS: Honestly, I -- I don't  
24 remember. It's -- it's way back. Could have  
25 been just the numbers that we got. I don't

1 remember exactly how we decided on the wording  
2 of -- of the comment.

3 BY MR. GALLAGHER:

4 Q If we go back one page to Page 2522,  
5 look at Table 6, which looks like is presenting  
6 pooled relative risks of hematopoietic cancers of  
7 hair dye use.

8 THE COURT REPORTER: I'm sorry. Can  
9 you repeat that?

10 BY MR. GALLAGHER:

11 Q Table 6 is presenting the pooled  
12 relative risks of hematopoietic cancers in hair dye  
13 use, correct?

14 A Yes.

15 Q Are these the numbers that -- that  
16 you're referring to that you would have looked at to  
17 decide the -- the causal effect is too weak?

18 MR. NIGH: Form objection. That  
19 misstates the -- the evidence of the prior  
20 document.

21 THE WITNESS: Yes. We probably looked  
22 at these numbers to come up with a conclusion.

23 BY MR. GALLAGHER:

24 Q What does it mean for -- for the  
25 relative risk to be --

1 THE COURT REPORTER: To be what?

2 MR. GALLAGHER: One.

3 THE WITNESS: One means there's no  
4 effect. There is no causal link.

5 BY MR. GALLAGHER:

6 Q Is the relative risk looking at a  
7 causal link or looking at an association?

8 A Well, again, for the purposes of this  
9 paper -- this academic paper, you can use  
10 association, if you will. And so a relative risk of  
11 1.0 would be no association.

12 Q Okay. And then I guess more broadly,  
13 the concept of the relative risk generally is  
14 looking at an association. It's not determinative  
15 of causation, correct?

16 MR. NIGH: Form objection.

17 THE WITNESS: No, I disagree with  
18 that. A relative risk is just a measure of  
19 effect. I mean, if you have -- you could have  
20 a relative risk from a very well-designed  
21 randomized trial, which is a, you know, true  
22 experiment. That relative risk would probably  
23 mean, to a high degree of certainty, a  
24 causation.

25 So it's not the relative risk --

1           whether it's a relative risk or the odds ratio  
2           that's presenting the effect size. It's the  
3           study design, and all the other factors that  
4           have gone into the study design, and the  
5           methodology that would tell you whether you  
6           believe the numbers are a causal blame versus  
7           an association.

8       BY MR. GALLAGHER:

9           Q           And so what -- what factors -- how do  
10          you determine whether a study is -- is being used  
11          to -- to evaluate an association versus being used  
12          to evaluate causation?

13                   MR. NIGH: Form objection.

14                   THE WITNESS: So if I'm looking at one  
15          study, I look at the methodology, the -- the  
16          way -- you know, the type of biases that may  
17          have played and whether those biases actually  
18          would reverse the direction of the effect side,  
19          would change the results or not. If I'm  
20          looking at a more broader question, then I am  
21          looking at the totality of the evidence.

22                   So again, one study from a journal, I  
23          kind of look at it differently than, you know,  
24          a real-life broader question, where I have to  
25          decide whether the substance causes --

1 THE COURT REPORTER: Whether the  
2 substance causes what?

3 THE WITNESS: Whatever outcome that we  
4 are looking at.

5 BY MR. GALLAGHER:

6 Q If in this article, we go ahead to  
7 Page 2524. In the middle column, the last full  
8 paragraph starts "The borderline effect." In this  
9 section of your paper, you wrote, "The borderline  
10 effect observed for brain tumors and ovarian cancer  
11 is based on the pooling of only two studies and does  
12 not permit a meaningful assessment of the risk."

13 Do you see that?

14 A Yes.

15 Q So you agree that, here, only looking  
16 at two studies wasn't -- wasn't sufficient to be  
17 able to evaluate the risk of hair dye for  
18 development of brain tumors and ovarian cancer,  
19 correct?

20 MR. NIGH: Form objection.

21 THE WITNESS: I mean, that's what we  
22 have. And again, you have to factor in a  
23 number of, I think, points. One is that my  
24 knowledge in causal inference in 2005 was not  
25 the same as it is now, so I may have done



1 things differently.

2 And a lot of what we write in these  
3 academic papers is also influenced by the  
4 editors who tell us, sort of, what type of  
5 wording to use, sometimes.

6 So, you know, yes, that's what we say  
7 here on this specific paper, and that's what  
8 was said. But I think there are sort of  
9 caveats to that.

10 BY MR. GALLAGHER:

11 Q Do you disagree with this statement in  
12 your paper?

13 A I don't disagree that that's what we  
14 said. But, again, the specific wording of that  
15 statement -- going back, I'm not sure what  
16 discussions we had -- could have been also  
17 influenced by the editors wanting us to sort of  
18 lower the tone, perhaps. Or in this case, you know,  
19 it is -- it could have been possible -- I'm not  
20 familiar with this area right now, with this area of  
21 hair dye and cancers.

22 But back then, it would have been  
23 feasible to say that with two studies, it's not a  
24 meaningful risk based on the data that we had then.

25 Q So you made -- do you believe that the

1 editors asked you to change the wording of this  
2 specific sentence in this paper?

3 A I -- I don't know.

4 MR. NIGH: Form objection.

5 THE WITNESS: I'm not saying that they  
6 did. I'm just saying sometimes in academic  
7 writing, if I want to say -- if I believe from  
8 my study that this drug causes this disease, at  
9 times we are -- we do receive pushback for,  
10 sort of, a lighter tone in that -- in  
11 presenting that statement.

12 And I don't know if this happened here  
13 or not, but I'm just saying that it's -- it  
14 could have been possible that this sentence  
15 came up with my contribution, my other authors'  
16 contribution and potentially the contribution  
17 of other editors as well.

18 BY MR. GALLAGHER:

19 Q In your academic work, when you're  
20 submitting articles for publication, do you allow  
21 editors to change the language of the article that  
22 you have written?

23 MR. NIGH: Form objection.

24 BY MR. GALLAGHER:

25 Q To something that you don't agree

1 with?

2 MR. NIGH: Form objection.

3 THE WITNESS: Well, it's a collective  
4 agreement. They make suggestions, and we look  
5 at the suggestions. And we agree or disagree.  
6 So it's -- you know, it's in -- you know,  
7 different situations are different.

8 MR. GALLAGHER: Okay. We can take  
9 this -- take this exhibit down.

10 Let's mark as Exhibit 4 your invoices.

11 THE WITNESS: Okay.

12 MR. GALLAGHER: Which, I believe, they  
13 provided -- were provided through the  
14 plaintiffs' counsel in response to the document  
15 requests.

16 (Whereupon, Exhibit 4 was marked for  
17 Identification.)

18 MR. GALLAGHER: That will be uploaded  
19 shortly.

20 BY MR. GALLAGHER:

21 Q Dr. Etminan --

22 MR. GALLAGHER: If we can go to the  
23 last page of this collection of invoices. I  
24 believe they are in reverse chronological  
25 order.

1 BY MR. GALLAGHER:

2 Q Dr. Etminan, does this refresh your  
3 recollection as to when you first spoke with  
4 plaintiffs' counsel about this case?

5 A Yes, probably around those dates,  
6 around those dates or maybe a bit before.

7 Q Okay. Around the time that you first  
8 became involved in this case, did plaintiffs'  
9 attorneys send you any documents?

10 A They -- yeah. I mean, they may have  
11 sent me some articles on the topic, and then as we  
12 went along, there were more documents that I  
13 reviewed.

14 Q Okay. Are -- are some of the articles  
15 that they provided to you articles that you cited in  
16 your report?

17 A I mean, I did -- I did my own  
18 systematic search. Some of the articles at the end  
19 would have -- could have been, you know, also the  
20 ones that they may have provided as well. But I  
21 didn't go with what they gave me. I went with my --  
22 the articles that came out of my systematic review.

23 Q Okay. Have you ever seen any of these  
24 articles prior to being involved in this litigation?

25 A I can't recall. I mean, I read a lot

1 on different topics.

2 MR. GALLAGHER: Let's mark as  
3 Exhibit 5 a copy of your report.

4 (Whereupon, Exhibit 5 was marked for  
5 Identification.)

6 BY MR. GALLAGHER:

7 Q Is it up? Do you have it there?

8 A Yeah, I have it.

9 Q Okay.

10 A Yes.

11 Q If you go up to page -- let's start at  
12 Page 12 of your report.

13 A Okay.

14 Q At the bottom, Section 8.1, you talk  
15 about a search strategy and study ascertainment. Do  
16 you see that section?

17 A Yes.

18 Q Is this the search strategy that you  
19 were just referring to for your identification of --  
20 of articles?

21 A Sorry. I lost you there. What was  
22 the question?

23 Q Sure. A few minutes ago, you had  
24 referenced, I think you called it a systematic  
25 search that you had done?

1 A Yes.

2 Q Is this the search strategy that you  
3 are referring to?

4 A Yes.

5 Q How did you come up with this  
6 particular search strategy?

7 A Well, I mean, I have done a lot of  
8 search strategies for my work, so I -- the question  
9 is on the risk of cancer and --

10 THE COURT REPORTER: I'm sorry -- and  
11 what?

12 THE WITNESS: NDMA.

13 So I identified the MeSH terms, the  
14 medical subject heading terms that would  
15 capture NDMA and combined it with cancer,  
16 including different types of cancer, and  
17 restricted it to epidemiological studies  
18 because those are the type of studies that I  
19 wanted to look at. So in a nutshell, that was  
20 the structure of the search.

21 BY MR. GALLAGHER:

22 Q Okay. And then if we go to the next  
23 page, Page 13, it's referring to study inclusion and  
24 exclusion criteria. Do you see that?

25 A Yes.

1 Q How did you come up with the inclusion  
2 and exclusion criteria?

3 A In order to, again, assess a causation  
4 for this question, I needed the studies to have  
5 presented some sort of an effect size, like the  
6 relative risk or an odds ratio or hazard ratio, have  
7 identified the outcome, cancer, and also have -- it  
8 has to have measured NDMA because I don't want to  
9 mix -- did not want to mix studies that included  
10 other carcinogens with NDMA. So that had to be one  
11 of the key criteria.

12 And I think those are the main  
13 criteria that I included.

14 Q Okay. What do you mean when you say  
15 you didn't want to use studies that mixed other  
16 carcinogens with NDMA?

17 A Well, you have a lot of studies on  
18 diet and processed food that also have looked at  
19 cancer that we know that -- for example, you know,  
20 red meat that could have NDMA, but it could also  
21 have other carcinogens that also contribute to  
22 cancer. So I wanted -- I wanted this study to  
23 specifically look at NDMA and cancer.

24 Q Okay. But the -- but the study -- so  
25 if the study is looking at red meat, any study that

1 is -- is looking at a causal association of dietary  
2 intake of red meat and cancer is going to include  
3 exposure to other carcinogens, correct?

4 MR. NIGH: Form objection.

5 THE WITNESS: Yes. There are -- there  
6 are carcinogens in red meat. But my interest  
7 is looking at the risk of cancer with the NDMA  
8 component. And if the study did not measure  
9 NDMA, sort of, separately, then it is very  
10 difficult to draw a causal relation between the  
11 NDMA and cancer in the meat product or other  
12 carcinogens and cancer in the meat product.

13 BY MR. GALLAGHER:

14 Q Okay. If you look under "Study  
15 Exclusion Criteria," the sentence immediately after  
16 the bolded underlined sentence. It says, "Moreover,  
17 lack of quantifying or categorizing (low versus  
18 high) NDMA/NDEA amounts in these studies will make  
19 it difficult to necessarily draw a causal link."

20 Do you see that?

21 A Uh-huh.

22 Q So were you only looking for studies  
23 that would support the conclusion of a causal link?

24 MR. NIGH: Form objection.

25 THE WITNESS: No, I'm not sure -- I'm



1 not clear on your question. So the sentence  
2 says, "Studies of meat intake where NDMA was  
3 not measured."

4 Again, if -- if the study is looking  
5 at meat and that -- that meat product has NDMA  
6 and other carcinogens and they show a risk with  
7 cancer, we can never tell what caused the  
8 cancer. Was it the NDMA component or the other  
9 components? So those studies that did not  
10 specify NDMA measurement were excluded.

11 BY MR. GALLAGHER:

12 Q Okay. Did you -- did you review or  
13 consider studies that were not cited in your report?

14 A You mean to reach my conclusion in the  
15 report?

16 Q We'll start with it more broadly.  
17 Did you review and consider studies  
18 that were not cited in your report?

19 A I -- I reviewed studies that met my  
20 inclusion criteria that were included in my report.

21 Q So -- but were there -- were there  
22 studies that met your inclusion criteria that you  
23 reviewed that you haven't cited in your report?

24 A I don't believe so. If it's not in  
25 the report, it's because it didn't have the

1 inclusion criteria. For example, it, you know, did  
2 not provide odds ratios or relative risks or NDMA  
3 levels. That -- I mean, that's -- that's why they  
4 were not in the report.

5 Q Okay. Some of the -- of the papers  
6 that you cited in your report are occupational  
7 studies, correct?

8 A Correct.

9 Q What is "occupational studies"?

10 A Occupational epidemiological studies  
11 are studies that -- that look at risk of, whether  
12 it's cancer, or it could be cardiovascular disease,  
13 in people who are exposed to an occupational  
14 exposure, so -- you know, people working in  
15 factories or rubber factories or, you know, hair dye  
16 factories. I mean, those would be considered  
17 examples of occupational exposure.

18 Q And the occupational studies that you  
19 looked at for your report were looking at people  
20 working in rubber factories, correct?

21 A Yes, the Hidajat studies and a couple  
22 of other ones that --

23 THE COURT REPORTER: I'm sorry. The  
24 what studies?

25 THE WITNESS: Hidajat, spelled

1 H-i-d-a-j-a-t.

2 BY MR. GALLAGHER:

3 Q And are -- how -- for -- for people  
4 working in the rubber industry, how many different  
5 carcinogens are they exposed to by virtue of working  
6 in a rubber factory?

7 MR. NIGH: Form objection.

8 THE WITNESS: They could be different  
9 carcinogen exposures.

10 BY MR. GALLAGHER:

11 Q Do you have an estimate for how many  
12 different carcinogens they're exposed to?

13 MR. NIGH: Form objection.

14 THE WITNESS: No, I don't.

15 BY MR. GALLAGHER:

16 Q So you don't know -- you reviewed --  
17 you reviewed a few of these occupations studies, but  
18 you don't know how many different carcinogens the  
19 rubber workers are exposed to by virtue of working  
20 in a rubber factory?

21 MR. NIGH: Form objection.

22 THE WITNESS: I don't remember --

23 MR. NIGH: Hold on. Hold on. Let me  
24 object to the form first. Form objection.

25 Go ahead, Doctor.

1 THE WITNESS: I don't remember the  
2 specific numbers, but I think it's important to  
3 know, and I agree with you, that they would be  
4 exposed to a -- a number of different  
5 carcinogens.

6 BY MR. GALLAGHER:

7 Q Okay. In these -- in these  
8 occupational studies -- strike that. Let's go ahead  
9 and mark them, first.

10 MR. GALLAGHER: So let's mark as  
11 Exhibit 6 the McElvenny article 7 is the Straif  
12 article.

13 THE COURT REPORTER: Is the what  
14 article?

15 MR. GALLAGHER: Straif, S-t-r-a-i-f  
16 article.

17 And Exhibit 8 will be the Hidajat  
18 article.

19 (Whereupon, Exhibit 6 was marked for  
20 Identification.)

21 (Whereupon, Exhibit 7 was marked for  
22 Identification.)

23 (Whereupon, Exhibit 8 was marked for  
24 Identification.)

25 THE COURT REPORTER: Can I take one

1 minute? I don't need to go off the record.

2 Can I take one minute?

3 MR. GALLAGHER: Why don't we go ahead  
4 and go off the record for a minute?

5 THE VIDEOGRAPHER: The time is now  
6 9:09. This ends Media Unit Number 1. We're  
7 going off the record.

8 (Whereupon, a short break was taken.)

9 THE VIDEOGRAPHER: The time is now  
10 9:11. This begins Media Unit Number 2. We're  
11 back on the record.

12 BY MR. GALLAGHER:

13 Q Okay. Dr. Etminan, we have marked as  
14 Exhibits 6, 7 and 8 three articles you cited in your  
15 report that are all occupational studies.

16 A Yes.

17 Q McElvenny paper, the Straif paper and  
18 the Hidajat paper. Do you see those?

19 A Yeah.

20 MR. NIGH: We don't -- I don't see  
21 Number 8 in the Dropbox, in the chat, I mean.  
22 There we go. Just came up.

23 MR. GALLAGHER: Sorry. It was a bit  
24 late.

25

1 BY MR. GALLAGHER:

2 Q And each of these three papers is  
3 looking at -- are occupational studies looking at  
4 risk of cancer in workers at rubber factories,  
5 correct?

6 A Generally speaking, they are, but they  
7 are a little different in terms of the study design.

8 Q When you say they're a little  
9 different, do you mean each of the studies is  
10 slightly different from the other study in their  
11 study design?

12 A Well, I mean, the main difference  
13 between McElvenny and Hidajat is that McElvenny just  
14 looked at cancer with occupational exposure, whereas  
15 Hidajat actually teased out the NDMA exposure  
16 component, looked at different -- those categories  
17 for each cancer, and took a number of methodological  
18 steps to reduce potential biases that McElvenny did  
19 not do.

20 Q Okay. You included McElvenny in --  
21 why did you include McElvenny in your report?

22 MR. NIGH: Form objection.

23 THE WITNESS: I -- I wanted to also  
24 just briefly touch on other occupational  
25 studies as well, because if I hadn't, then

1           there would be a question of, you know, why did  
2           you -- why did you only look at Hidajat. So I  
3           wanted to mention that there are these  
4           occupational studies as well, but my focus was  
5           on the study by Hidajat because it met the main  
6           inclusion criteria for my question.

7           Q           Did the McElvenny study -- article,  
8           though, meet your exclusion criteria?

9           A           It may have because they did not  
10          include NDMA. And again, I just mentioned that it's  
11          not in my main analytical framework of evidence when  
12          I'm deciding on the causal question. But I just  
13          thought to introduce, you know, just to mention it  
14          as background that there -- you know -- and it is  
15          part of Hidajat -- in a way related to Hidajat.  
16          It's an older version of Hidajat, so I thought I  
17          should mention it.

18          Q           So you included the McElvenny article  
19          in your report even though it met the exclusion  
20          criteria for studies that should be excluded?

21          A           Again --

22                   MR. NIGH: Form objection.

23                   THE WITNESS: The -- the -- the  
24          inclusion criteria is -- is mainly used to form  
25          my opinion, which, again, is included in the

1           Bradford Hill criteria and the main, sort of,  
2           framework of my opinion on the causal effects.  
3           I mention -- I briefly mentioned McElvenny and  
4           Straif because they are also other -- the other  
5           relatively well-cited occupational exposure  
6           cancer studies, and I mentioned them as, you  
7           know, background in my -- in the paragraph.

8       BY MR. GALLAGHER:

9           Q           But I am correct that McElvenny meets  
10          the exclusion criteria that you set out for studies  
11          that should be excluded?

12          A           Yes.

13          Q           Okay. For these occupational studies,  
14          the method of exposure was primarily through  
15          inhalation or skin contact. Would you agree with  
16          that?

17                       MR. NIGH: Form objection.

18                       THE WITNESS: Yeah.

19       BY MR. GALLAGHER:

20          Q           Okay. And that method of exposure is  
21          different from the method of exposure that's at  
22          issue in this case, correct?

23          A           The method of exposure is different,  
24          but my -- the question, the general causation  
25          question that I -- that my report refers to does not



1 specify cause of cancer with NDMA with respect to  
2 different rounds of exposure. It refers to,  
3 generally speaking, exposure. And we mean systemic  
4 exposure, which could be mouth or through the skin  
5 or through inhalation cause cancer.

6 Q Okay. So the question that you were  
7 evaluating was not whether NDMA ingested orally  
8 could cause certain cancers; is that correct?

9 MR. NIGH: Form objection.

10 THE WITNESS: No, that's not -- that's  
11 not what I said. The question that I addressed  
12 was: Does exposure to NDMA and exposure would  
13 mean NDMA that gets in to the body systemic --  
14 systemically absorbed NDMA, which can be  
15 through oral, inhalation, skin. I think mainly  
16 those are the -- the main routes of the  
17 exposure. Does builds -- does exposure to NDMA  
18 through any of those routes that make it  
19 systemic in the body cause cancer.

20 BY MR. GALLAGHER:

21 Q So is -- the question that you were  
22 addressing was more broadly, does exposure to NDMA  
23 in any manner have an association or potentially  
24 lead to cancer; is that correct?

25 A Any matter that -- that leads to

1 systemic absorption. So if I could clarify, so  
2 if -- if -- if for -- let's say, hypothetically,  
3 there was a study where a person inhaled NDMA for  
4 one day, that -- that would not really be systemic  
5 absorption of NDMA. But if in a study of a 40-year  
6 follow up, people are exposed to NDMA through skin  
7 and inhalation, you can be sure that they are,  
8 throughout the time of follow up, are getting  
9 exposed to NDMA systemically.

10 Q Okay. Let me unpack that a little  
11 bit.

12 So you're referring to a time frame  
13 component?

14 A Yes, I mean the studies that I  
15 included are epidemiological studies. They are --  
16 either follow a patient forward or have asked about  
17 their intake. So they -- they have been followed  
18 for a time, and these patients have been exposed to  
19 NDMA over time.

20 Q Okay. Do you agree with me that  
21 the -- that the method of -- what the method of  
22 exposure is to NDMA can have an impact on what  
23 tissues in body are exposed to NDMA?

24 A Can you clarify the question, please?

25 Q Sure. I guess do you have any

1 understanding -- let me ask it this way: Do you  
2 have any understanding whether different tissues are  
3 exposed to NDMA if the exposure is through  
4 inhalation versus through skin contact versus oral  
5 ingestion?

6 A From animal studies, we know that it  
7 has caused cancer from those different routes of  
8 administration in animals. In humans, again,  
9 exposure to NDMA where it gets into your system can  
10 affect different organs, just like smoking --  
11 primarily smoking causes lung cancer. But we have  
12 evidence that it can also cause other cancers.

13 So it's not that -- although it's  
14 mostly affecting the lung, that the carcinogen is  
15 probably affecting other -- other organs as well.

16 Q Okay. I understand what you're  
17 saying, but do you have any understanding whether  
18 the method by which a person is exposed to NDMA  
19 impacts the tissues that are actually exposed to  
20 NDMA?

21 MR. NIGH: Form objection.

22 THE WITNESS: You mean like a  
23 toxicology study or an epidemiological study  
24 that looks at different tissue levels with  
25 respect to cancer? Can you, maybe, elaborate a

1 little bit about the type of study you're  
2 asking about?

3 BY MR. GALLAGHER:

4 Q Sure. I don't think I'm asking about  
5 a study, necessarily. I'm asking if you have an  
6 understanding of whether the -- do you have any  
7 understanding whether an exposure to NDMA through  
8 oral ingestion versus exposure through inhalation  
9 has any differences in the tissues that are  
10 ultimately exposed -- ultimately exposed to NDMA?

11 A No. I mean, I think that's -- that's  
12 sort of like a toxicology type of question. I don't  
13 know of any details of specific concentration of  
14 NDMA in each organ, no.

15 Q Okay. Let's look at the Straif  
16 article that's Exhibit 7.

17 So in your report, you say -- you say  
18 that there with an increase in the risk of --

19 THE COURT REPORTER: In the risk of --  
20 I'm sorry. In the risk of what?

21 MR. GALLAGHER: All cancer deaths.

22 THE COURT REPORTER: I'm not  
23 understanding.

24 MR. GALLAGHER: I'll repeat the  
25 question.

1 BY MR. GALLAGHER:

2 Q In your report, you say about the  
3 Straif study that there was an increase in the risk  
4 of all cancer deaths. And you identify the relative  
5 risk of 1.4 with the confidence interval of 1 to  
6 1.8?

7 A Let me find that, just one second.

8 Q Okay. If you look at Page 14 of your  
9 report.

10 A Okay. 14, okay. Okay.

11 Q So you agree that this -- this was not  
12 statistically significant?

13 MR. NIGH: Form objection.

14 THE WITNESS: I think it just missed  
15 the statistical significance because it -- the  
16 lower balance starts with 1.0.

17 BY MR. GALLAGHER:

18 Q So it did miss the statistical  
19 significance because the lower bound of the  
20 95 percent --

21 THE COURT REPORTER: Can you repeat  
22 that, please?

23 MR. GALLAGHER: Sure.

24 BY MR. GALLAGHER:

25 Q Sure. It missed statistical

1 significance because the lower bound of 95 percent  
2 confidence interval included 1.0, correct?

3 A Correct.

4 Q And as we discussed previously, a  
5 relative risk of 1.0 means there's no association  
6 between the exposure and the risk that's being  
7 validated, correct?

8 A Well, the relative risk is 1.4. The  
9 lower bound is 1.0. And, again, it speaks to  
10 precision. I cannot -- I cannot exclude this  
11 size -- this relative risk of 1.4 and just say it's  
12 not -- because it's not statistically significant,  
13 there is no harm. Again, I -- I think we spoke  
14 about the caveats of interpretation of what the  
15 P value is and statistical significance really  
16 means.

17 So I mean, it is a 1.4 relative risk  
18 with those confidence intervals.

19 Q Okay. If you were to present data to  
20 a peer --

21 THE COURT REPORTER: To appear what?  
22 BY MR. GALLAGHER:

23 Q To a peer-reviewed journal, like this  
24 where the confidence interval includes 1.0.

25 A Uh-huh.

1 Q Would you expect that peer-reviewed  
2 journal would not let you say that there was  
3 statistically significant association?

4 MR. NIGH: Form objection.

5 THE WITNESS: Again, it -- it depends  
6 on the journal on the editorial board. The  
7 statistical significant, sort of, misnomer, if  
8 you will, that I talked about, is relatively  
9 recent. And the American Statistical  
10 Association put out this correction on the  
11 interpretation of this -- this topic in 2016.  
12 So it will take a while before most editorial  
13 boards and editors really come to grasp of  
14 what -- what this concept means.

15 So, again, because up until now, a lot  
16 of these editors are sort of interested in  
17 statistical significance versus nonstatistical  
18 significance. It's possible that some journals  
19 still ask that.

20 BY MR. GALLAGHER:

21 Q I believe we've talked about this a  
22 couple of times now. When you submit an article for  
23 consideration to be published in a peer-reviewed  
24 journal, there's review by, you call them editors;  
25 is that right?

1           A           There's usually a peer review of two  
2           or more peers, external reviewers, and then there  
3           is -- yes, there is an editor that also reviews it.

4           Q           And when -- what is the purpose of the  
5           peer-review process?

6           A           The peer-review process is to try to  
7           ensure as much as possible, and sometimes that does  
8           not happen, but the process is there to ensure that  
9           the research is -- is vetted and -- and checked  
10          before it's published.

11          Q           Okay. And when you -- when you submit  
12          an article for the peer-review process, is it  
13          sometimes either the peer reviewers or the editors  
14          ask you to make changes to the article?

15          A           Yes, usually they do.

16          Q           And part of the purpose of that peer  
17          review process and the changes that they may ask for  
18          is to improve the scientific accuracy and validity  
19          of what's being published, right?

20          A           That is correct.

21                      MR. NIGH: Objection.

22          BY MR. GALLAGHER:

23          Q           Okay. And the report, Exhibit 5, that  
24          you submitted in this litigation, your expert  
25          report, that was not submitted through peer review,



1 correct?

2 A No.

3 Q Looking at the Straif article, Exhibit  
4 7, specifically on Page 181.

5 A Yes.

6 Q I'll come back to that later.

7 MR. GALLAGHER: Let's take maybe a  
8 10-minute break right now.

9 THE WITNESS: Sure.

10 THE VIDEOGRAPHER: The time is  
11 9:33 a.m. and we're going off the record.

12 (Whereupon, a short break was taken.)

13 THE VIDEOGRAPHER: The time is now  
14 9:47. We're back on the record.

15 BY MR. GALLAGHER:

16 Q Welcome back, Dr. Etminan.

17 A Thank you.

18 Q If you look at Page 14 of your report,  
19 the paragraph about -- where you're writing about  
20 the McElvenny article?

21 A Uh-huh.

22 Q Is that -- this is Exhibit 5, the --  
23 towards the bottom of that paragraph, you say,  
24 "These men might have been exposed to carcinogens  
25 other than NDMA and NDEA"?

1 A Yes.

2 Q And, in fact, working in the rubber  
3 factories, they probably were exposed to many  
4 carcinogens other than NDMA and NDEA, right?

5 A Yes, possible.

6 Q And the same would be true for the  
7 rubber workers who are study subjects of the Straif  
8 article?

9 A Yeah.

10 Q And the same would be true for the  
11 cohort of rubber workers that were subjects of the  
12 Hidajat article, right? Those men would have been  
13 exposed to many carcinogens other than NDMA and  
14 NDEA, correct?

15 A If I could clarify, so, yes, all of  
16 these men were working in these factories, and they  
17 were exposed to a number of carcinogens, including  
18 NDMA. However, Hidajat was the only one that  
19 actually quantified NDMA in different levels. And  
20 if -- if you're inferring that there could be a  
21 potential risk of cancer with other carcinogens,  
22 that is true. However, we have to actually know  
23 that the -- the men who are on the highest NDMA  
24 exposure in the Hidajat study are actually exposed  
25 more to other carcinogens than the men in the lower

1 NDMA exposed group.

2 In other words, for carcinogens -- for  
3 other carcinogens to introduce this bias for  
4 measurement in this study, you have to be able to  
5 show that the NDMA, the highest NDMA category met  
6 were getting -- were getting more exposure to those  
7 carcinogens than the control group.

8 And I don't think -- in other words,  
9 there is what we call a differential, sort of,  
10 measurement. In other words, it's affecting one  
11 group more, that's why we see more cancers. But  
12 that's not -- I mean, there's no reason to believe  
13 that. This is a large population study in the UK.  
14 All these men are in the factory. They are all  
15 being exposed to different carcinogens probably at  
16 the same rate. I mean, there is no -- there is no  
17 reason to believe that the ND -- the highest NDMA  
18 group that has -- shows higher cancer rates were  
19 also exposed to other carcinogens more than the  
20 other -- they were probably exposed at equal rates.

21 Q Okay. Well, let's look at the Hidajat  
22 studies. That's Exhibit 8.

23 And if you look at -- first off, let's  
24 look at the first page, the right-hand column,  
25 the -- the last paragraph starts off -- it says,

1 "Exposures vary throughout the rubber manufacturing  
2 process."

3 Do you see that?

4 A Yes.

5 Q So that's following a list of several  
6 potential -- exposures to potential carcinogens that  
7 exist in the -- in the rubber factory, and it's  
8 saying that the exposures vary throughout the rubber  
9 manufacturing process, right?

10 A What was your -- the last part of your  
11 comment? Sorry. I couldn't hear.

12 Q It's saying here that the exposures to  
13 these potential carcinogens vary throughout the  
14 rubber manufacturing process, right?

15 A Yes, they vary, yeah.

16 Q And then going to the next page,  
17 Page 251, the right-hand column, the top heading,  
18 "Exposure Assessment" -- first off, this is looking  
19 at a study of rubber workers in the UK, correct?

20 A Yes.

21 Q The cohort of -- it was male rubber  
22 factory workers in the UK aged 35 years or older as  
23 of 1 February 1967, and that's on this Page 251  
24 under "Materials and Methods"?

25 A Uh-huh.

1 THE COURT REPORTER: Is that yes?

2 THE WITNESS: Yes.

3 BY MR. GALLAGHER:

4 Q So the first sentence under "Exposure  
5 Assessment," says, "Exposure assessment was based on  
6 estimates from the EU-EX-ASRUB database of  
7 measurements of compounds in rubber factories in  
8 Europe," right?

9 A Uh-huh. Yes.

10 Q So this is where they're getting the  
11 estimates for each of the compounds that they're  
12 looking at, including NDMA, right?

13 A Yes.

14 Q Okay. And that's citing to  
15 Reference Number 18, and if we go forward to  
16 Page 258 on the right-hand column, you see  
17 Reference 18. And that's an article by DeVocht as  
18 the lead author, right?

19 A Yeah.

20 MR. GALLAGHER: Let's mark as  
21 Exhibit 9 the DeVocht article.

22 (Whereupon, Exhibit 9 was marked for  
23 Identification.)

24 MR. GALLAGHER: Let me know when it  
25 shows up in the chat.

1 THE WITNESS: Yeah, it just showed up.

2 BY MR. GALLAGHER:

3 Q If we go to Page 694 under -- under  
4 "Results"?

5 A Uh-huh.

6 Q And this is explaining that -- well, I  
7 guess, first off, this is the article that Hidajat  
8 is citing to as the source of the estimates for  
9 exposures, including the exposures to NDMA, correct?

10 A Yes.

11 Q Okay. And under "Results," it's  
12 describing the EX-ASRUB database and explaining that  
13 "the measurements in the database have been  
14 collected from very different sources in the  
15 participating countries."

16 Did I read that correct?

17 A That is correct, but they -- they  
18 do -- there's statistical modeling that is mentioned  
19 in their method. They do correct for a lot of those  
20 heterogeneity between country measurements. So I  
21 found that modeling quite robust. Not that -- not  
22 that it doesn't have -- I mean, every study has  
23 limitations, but I found that -- that part of what  
24 they did was quite strong in terms of correcting for  
25 those differences that we just mentioned of exposure

1 in different countries.

2 Q Who -- who did the corrections that  
3 you're referring to?

4 A Well, they used the random effects, if  
5 you look at the -- if you look at the method -- the  
6 statistical methods, I believe.

7 Q Which article are you looking at?

8 A DeVocht.

9 Q Doctor, are you referencing -- are you  
10 talking about DeVocht, or are you talking about  
11 Hidajat?

12 A No, DeVocht.

13 Q Maybe let's look on the Page 697, and  
14 if we can start -- start in the left-hand column,  
15 the bottom paragraph that's going to then carry over  
16 to the right-hand column?

17 A Okay.

18 Q Do you see that, it says, "Not only  
19 the number of collected measurements and the time  
20 periods when they were collected differed between  
21 the different countries, but large differences were  
22 also found in the type of chemical agents collected  
23 depending on nationally set priorities and research  
24 interests of particular investigators," right?

25 A I see that.

1 Q Okay. Then it goes on to say, "For  
2 example, N-nitrosamine measurements were primarily  
3 collected in Germany, while in the UK, measurements  
4 of rubber process dust and rubber fumes were made."

5 Do you see that?

6 THE COURT REPORTER: I'm sorry. While  
7 in the UK, measurements of...

8 MR. GALLAGHER: Rubber process dust  
9 and rubber fumes were made.

10 BY MR. GALLAGHER:

11 Q Do you see that?

12 A Yes.

13 Q So N-nitrosamine measurements were  
14 primarily coming from exposures in factories in  
15 Germany? That's where the estimates were coming  
16 from in DeVocht, correct?

17 MR. NIGH: Object to form.

18 BY MR. GALLAGHER:

19 Q Correct? Am I correct -- the  
20 measurements of N-nitrosamine that are being used in  
21 DeVocht are primarily collected from rubber  
22 factories in Germany?

23 MR. NIGH: Object to form.

24 THE WITNESS: Can I have a few minutes  
25 just to read this section, if you allow -- if



1           you allow me?

2       BY MR. GALLAGHER:

3           Q           Sure. Sure. Take a minute.

4           A           Okay. So, yes, they do -- they do --  
5       they do list these limitations as you pointed out.  
6       However, I mean, one can argue that these  
7       limitations could also potentially underestimate the  
8       exposure of -- of what they have measured in their  
9       study.

10                   And, again, I go back to my original  
11       point. You're following -- you have 35,000 men for  
12       about -- sorry, 15,000 men for about 40 years. In  
13       order to produce results that are a major deviation  
14       from the risks that they have shown, you have to be  
15       able to actually show that one group was -- had, you  
16       know, a major measurement error in other carcinogens  
17       or NDMA more than the other group because this is a  
18       population-based study.

19                   And there is really no reason to  
20       believe that one group had these limitations and the  
21       other group did not. It probably occurred  
22       non-differentially in both groups over a long period  
23       of time.

24                   So yes, as they said, the study does  
25       have some limitations. But I think this limitation

1 does -- could actually mean the risk could be  
2 potentially higher because it's smaller -- perhaps,  
3 potentially a smaller quantity of NDMA was measured,  
4 so the techniques that they were talking about.

5 But overall, I think that the study's  
6 strengths, sort of, outweigh its limitations. But,  
7 I mean, that is a limitation that they discuss.

8 Q So you say that based on this  
9 limitation, they could have -- potentially could  
10 have underestimated any potential association, but  
11 they are -- based on that limitation -- they also  
12 could have overestimated any potential association,  
13 right? That's the nature of the limitation?

14 A Yes, it could go both ways, but I --  
15 I'm more -- again, I go back to my -- I'm more of a  
16 stronger believer in the fact that any major  
17 deviation from these results requires, you know, a  
18 large amount of measurement error over time only in  
19 one group and not the other group. Other  
20 limitations could perhaps change the effect size,  
21 you know, perhaps a little bit. But I don't see a  
22 relative risk of three or four, you know, coming  
23 down to one or -- or to the left of one. I don't --  
24 I don't see -- without having evidence of any major  
25 measurement error going on, I don't see those

1 results drastically changing.

2 Q Okay. You talked about measurement  
3 errors. So talking about the Hidajat study, the  
4 Hidajat article?

5 A Yes.

6 Q This is a cohort of men working in  
7 rubber factories in the UK.

8 A Right.

9 Q And --

10 A Right. By "measurement" there, I mean  
11 if one group is exposed, as you also agreed because  
12 of other potential carcinogens, if one group -- if  
13 there is a measurement error in NDMA in one group,  
14 say, the high users more than the lower users, or if  
15 there is more exposure of other carcinogens in one  
16 group versus the other, in the presence of those,  
17 there -- there could be a bias introduced.

18 But we don't have any evidence that in  
19 this long-followed-up large-sample study these  
20 errors only favored one group, let's say the high  
21 NDMA users and not the -- not the other -- not the  
22 control group. There is no evidence to believe  
23 that. It probably happened equally over time in  
24 both groups.

25 Q Okay. So you're talking about

1 measurement error and measurement of NDMA in the  
2 Hidajat study.

3 A And -- and exposure -- and exposure of  
4 other carcinogens, which was also brought up --

5 Q Okay.

6 A -- as well.

7 Q I want to talk for just a minute about  
8 the measurement of NDMA.

9 A Okay.

10 Q Hidajat -- Hidajat is a cohort of  
11 workers in rubber factories in the UK, right?

12 A Yes.

13 Q Hidajat did not measure the levels of  
14 NDMA to which any of -- to which those workers were  
15 exposed, right? It was based on estimates from this  
16 database, right?

17 A Correct.

18 MR. NIGH: Objection.

19 THE WITNESS: Measuring -- measuring  
20 direct NDMA for each subject and following them  
21 for 35 years is pretty much impossible, so  
22 that's -- that's the approach that they took.

23 BY MR. GALLAGHER:

24 Q Right. But Hidajat didn't take any  
25 measurements. Hidajat based -- Hidajat based their

1 exposure assessment on estimates from the EX-SARUB  
2 database.

3 A Yes, I think we've -- we've agreed on  
4 that, yes.

5 Q Okay. And now we're looking at  
6 DeVocht article, and there, the -- the measurements  
7 for N-nitrosamine primarily were collected in  
8 Germany, right?

9 MR. NIGH: Form objection.

10 THE WITNESS: Yes.

11 BY MR. GALLAGHER:

12 Q And they say that there were large  
13 differences in the time periods and large  
14 differences in the type of chemical agents collected  
15 depending on nationally set priorities and research  
16 interests of particular investigators, right?

17 A Right.

18 Q Okay. Further on here in the next  
19 paragraph right below that paragraph, it goes on to  
20 say in the DeVocht article, "Furthermore, measured  
21 concentrations cannot be compared directly between  
22 countries because of the differences in sampling  
23 devices used to measure exposures," right?

24 A Yeah. That's what they said, yeah.

25 Q So that's a further limitation.

1                   And then -- and then the bottom of  
2                   this page, it carries over to the next page, they  
3                   further say, "This makes it difficult to distinguish  
4                   between actual differences of exposure between  
5                   countries and differences in the performances of  
6                   different sampling devices that are known to exist,"  
7                   right?

8                   A               Yes.

9                   Q               So we don't know that the exposures  
10                  for N-nitrosamine, for NDMA, or for NDEA that were  
11                  included in this database from the DeVocht article,  
12                  are representative of the rubber factory that are  
13                  included -- the rubber factories in the UK that are  
14                  included in the Hidajat cohort, right?

15                  MR. NIGH:   Object to form.

16                  THE WITNESS:   Again, that -- that  
17                  could -- I mean, I believe this -- we don't.   I  
18                  believe the assumption would be that they  
19                  are -- I mean, it's Europe -- it's European  
20                  countries.

21                  If -- if they were using NDMA exposure  
22                  data from China and applying it to the UK, I  
23                  would be concerned.   But, here, yes, they don't  
24                  have exact measurements for each country.   But  
25                  again, there has to be a huge difference

1 affecting both the high NDMA and the low NDMA  
2 groups over 30 years to -- to shift the -- you  
3 know, create a major change in the results that  
4 Hidajat produced.

5 BY MR. GALLAGHER:

6 Q But that's a limitation that  
7 DeVocht -- the authors of the DeVocht article are  
8 acknowledging in this database, right?

9 A Yes.

10 Q Let's go back to the Hidajat article,  
11 on the first page of the article right under  
12 "Introduction."

13 A Okay.

14 Q It says -- starting off the article,  
15 first sentence, they say, "Employment in the rubber  
16 industry has been concluded to cause cancer by the  
17 International Agency for Research in Cancer (IARC)."

18 Do you see that?

19 A Yes.

20 Q Do you have any reason to disagree  
21 with that statement?

22 A No.

23 Q And, in fact, rubber -- workers in  
24 rubber factories in the UK are exposed to a variety  
25 of potential carcinogens, right?

1 A Yes.

2 Q And that includes rubber dust, rubber  
3 fumes, polycyclic aromatic hydrocarbons, aromatic  
4 amines, benzene, all of those, correct?

5 A Correct.

6 Q And that exposure is primarily by  
7 inhalation or direct contact with skin, right?

8 A Yeah.

9 Q Okay. The -- the Hidajat study  
10 didn't -- didn't control for all of these potential  
11 confounding exposures, did they?

12 A I wouldn't call them confounders  
13 because the specific definition of a confounder is a  
14 variable that has to be associated with both NDMA  
15 use and cancer. These are mostly risk factors which  
16 means that they are mostly causes of cancer.

17 And again, I go back to my point,  
18 major -- if you're inferring that these -- yes,  
19 these are all carcinogens. That's what IARC says,  
20 and I have -- I agree with what they're saying. But  
21 if you're inferring that these carcinogens  
22 contributed to the high relative risk of cancer that  
23 we see from Hidajat based on the high NDMA levels;  
24 again, I go back to my explanation of the type of  
25 bias that -- that needs to be created, has to be



1 differential, meaning that it has to -- we have to  
2 have data, or we have to intuitively think that  
3 these chemicals are only affecting the NDMA -- high  
4 NDMA category and not the control group. And  
5 there's no reason to believe that's the case.

6 Most probably, just inferring from  
7 what we know from the data from -- from the article  
8 of the cancer studies, that this long follow up,  
9 these -- these other carcinogens probably affect  
10 both the high NDMA -- well, it affects everyone in  
11 -- in the study, high NDMA group versus low NDMA  
12 group.

13 And when that happens in the  
14 epidemiological studies, it usually -- usually is an  
15 underestimation of the true effect. In other words,  
16 the risk, relative risk is 7, and it comes down to 5  
17 because of this error, this potential contamination  
18 in both groups, which we call "non-differential  
19 measurement error."

20 The bias that you, I think, are  
21 referring to is a case where all of these  
22 carcinogens are only affecting the high NDMA group  
23 and not the other group. And that just doesn't --  
24 you know, we don't have any data for that. It  
25 doesn't make a lot of sense why that would happen.

1                   So to answer your question, yes, a  
2                   number of these carcinogens were present in this --  
3                   in this study just because of the nature of the  
4                   exposure.

5                   But I don't think it would have  
6                   changed the results that much, because of this  
7                   presence of other carcinogens. Again, because there  
8                   is no reason to believe that it affects one group  
9                   and not the other group.

10           Q           Well, unless you control for these  
11           other exposures, you don't know if there's a  
12           differential effect or not?

13                   MR. NIGH: Form objection.

14           BY MR. GALLAGHER:

15           Q           Correct?

16           A           Can you repeat your question, please?

17           Q           Unless you control for these other  
18           exposures, you don't know whether there's a  
19           differential effect or not?

20                   MR. NIGH: Form objection.

21                   THE WITNESS: Well, I mean, it's --  
22                   it's gonna be very difficult to measure for all  
23                   of these variables. And, again, they're not --  
24                   we -- we control for -- we control for mainly  
25                   confounders. I'm not sure if all of these are

1 confounders in the true sense of the term,  
2 which is a variable that affects both the  
3 outcome and the exposure.

4 There are mainly risk factors, and  
5 risk factors are not -- not controlling for  
6 risk factors is not as detrimental as not  
7 controlling for confounders.

8 This is -- this is a very -- you know,  
9 it's a very difficult study to execute, and  
10 there's no -- there is no way to control for  
11 all of those variables. And I'm not -- again,  
12 I'm not sure if -- they're not true  
13 confounders, I'm not sure -- not controlling  
14 for them would affect the results, or at least  
15 a direction of the results, that much.

16 BY MR. GALLAGHER:

17 Q Okay. Understanding the distinction  
18 you're making between exposures to these other  
19 potential carcinogens and confounders, let's talk  
20 first about these other potential exposures. And  
21 we'll talk about confounders in a few minutes.

22 If the workers in a specific area of  
23 the rubber factory in -- in the UK are exposed to  
24 rubber fumes, polycyclic aromatic hydrocarbons,  
25 aromatic amines and NDMA, and half of those are

1 carcinogens and half of them are not, how do you  
2 separate which ones are, if you haven't controlled  
3 for those different -- for those exposures?

4 MR. NIGH: Form objection.

5 THE WITNESS: Again, that's -- that's  
6 very difficult to do. And, again, I go back to  
7 my previous point: In a large cohort of 15,000  
8 men with 35 years of follow up, you have to  
9 show consistently that the other carcinogens is  
10 only affecting the high NDMA users, through the  
11 35 years of follow up constantly in order for  
12 the effect of -- of other -- the other  
13 carcinogens to be reflected in the relative  
14 risk. That -- we don't have any data that  
15 that's happening. It doesn't make intuitive  
16 sense.

17 It makes sense that these men are  
18 exposed to these carcinogens, but in the span  
19 of a 35-year follow-up, it's probably affecting  
20 both the high NDMA and the low NDMA equally.  
21 And when that happens, that actually dilutes  
22 the -- the -- the relative risk that you're  
23 seeing.

24 So, again, we don't have -- there's no  
25 way to measure all the -- all these agents that

1           you mentioned for all these men and follow them  
2           for the 35 years. But because I don't believe  
3           it's affecting one group more than the other, I  
4           don't -- I don't see a major -- this potential  
5           limitation leading to a major bias.

6       BY MR. GALLAGHER:

7           Q           Well, you say you don't believe it's  
8           affecting one group more than another, but that's an  
9           assumption you're making, right?

10                   MR. NIGH: Object to form.

11                   THE WITNESS: It's not just an  
12           assumption. It's -- I mean, it's -- it's based  
13           on the -- the information you're given, this  
14           is -- this is rubber factory workers, 35 years  
15           of follow-up in the UK. And we are not  
16           giving -- we are not given any information  
17           that, you know, all of a sudden, this cohort,  
18           or at least part of the cohort, is exposed to  
19           this other carcinogen more, you know, in the  
20           high -- especially in the high NDMA group more  
21           than the other, the control group.

22                   So I -- I feel comfortable with the  
23           assumption because I -- I just can't see any  
24           sort of a logical reason as to why that would  
25           happen. It's a -- it's a large population

1 based study on the same cohort in the same  
2 country followed forward for 35 years.

3 BY MR. GALLAGHER:

4 Q Can we go for just a minute to your  
5 invoices again, which is Exhibit 4, I think? Is  
6 that right? Exhibit 4.

7 And if we look at Page 3 of 5, this is  
8 an invoice from May 5th of 2021.

9 Do you see the -- there's three  
10 entries on this invoice. The bottom entry looks  
11 like you spent three hours searching for  
12 methodologies to control for unmeasured confounding  
13 for the Hidajat study. Do you see that?

14 A Yes.

15 Q Why were you searching for  
16 methodologies to try to control for unmeasured  
17 confounding in the Hidajat study?

18 A Because I wanted to show how robust  
19 the -- the results would be in the absence of one  
20 uncontrolled confounded.

21 Q When you're saying you want to show  
22 how robust it is, you're assuming that the results  
23 are robust, but for unmeasured confounding factors,  
24 right?

25 MR. NIGH: Form objection.

1 THE WITNESS: Well, let me put it,  
2 then, another way. I wanted to know if there  
3 is -- how much change -- how much the results  
4 would change when I include -- when I  
5 assimilate this unmeasured confounder into the  
6 results.

7 BY MR. GALLAGHER:

8 Q Okay. And in order to do that, you  
9 had to go search for methodologies to control for  
10 those unmeasured confounders, right?

11 A Yes.

12 MR. NIGH: Form -- form objection.

13 BY MR. GALLAGHER:

14 Q It's not something that you -- you had  
15 a methodology that you -- you -- that you typically  
16 use, yourself, in your -- in your research?

17 MR. NIGH: Form objection.

18 THE WITNESS: Can you repeat the  
19 question, please?

20 BY MR. GALLAGHER:

21 Q You had to go search for methodologies  
22 because you didn't have -- you didn't have a  
23 methodology that you typically used for this type of  
24 looking at potential effects of unmeasured  
25 confounders, right?

1 MR. NIGH: Form, form objection.

2 THE WITNESS: No, I -- I used the  
3 E-value methodology which I had -- I have used  
4 actually before in my -- in my research  
5 studies. I just wanted to do another search  
6 just to see if there is any newer or perhaps  
7 better methodology than the E-value  
8 methodology. And I found that there isn't any,  
9 so I used the method that I have used, you  
10 know, a number of times in the past in my own  
11 research.

12 BY MR. GALLAGHER:

13 Q Okay. If we look at your report,  
14 Page 15?

15 A Yes.

16 Q And is this -- is this table part of  
17 what you're referring to in terms of looking at the  
18 effect of unmeasured confounders?

19 A Yes.

20 Q And walking through the table on the  
21 left-hand column, you've listed different specific  
22 types of cancer, right?

23 A Yes.

24 Q And in the middle column, you --  
25 you're listing hazard ratios without unmeasured



1 confounder. Where are you getting those numbers  
2 from?

3 A So by using this methodology that's  
4 published, if you include -- there is a formula  
5 where you include the -- for example, the stomach  
6 cancer is 1.72. If you include this in this  
7 formula, it tells you how large that unmeasured  
8 confounder has to be to eliminate the risk of 1.72.

9 So you can see for all the other  
10 cancers -- all the cancers listed, the -- the  
11 magnitude of the effect of that confounder has to be  
12 pretty large to reverse the -- the relevant risks on  
13 the left-hand column.

14 Q So I guess -- let me walk through it  
15 this way.

16 The left-hand column, those are -- are  
17 reporting hazard ratios that are coming from the  
18 Hidajat study; is that right?

19 A That's right.

20 Q Okay. And then in the right-hand  
21 column is where you're now calculating what -- what  
22 the hazard ratio for an unmeasured confounder would  
23 need to be in order to take the relative risk in the  
24 left-hand column down to one; is that right?

25 A Correct.

1 Q Okay. And Hidajat, they did not  
2 directly control for smoking, right?

3 A They did not, although -- they did  
4 not, although they said they simulated smoking data,  
5 and the results did not change.

6 Q They simulated smoking data, but they  
7 didn't control for smoking, right?

8 A No.

9 Q Would you consider smoking to be a  
10 potential confounder?

11 A So smoking is definitely a risk factor  
12 for cancer, and smoking, in order for it to be a  
13 confounder, has to also be potentially associated  
14 with NDMA exposure. So it could potentially be  
15 confounded, yes.

16 Q Okay. And another potential  
17 confounding factor would be family history of  
18 cancer?

19 A Yes, family history of cancer --  
20 again, so the family history of cancer is definitely  
21 a risk factor for cancer. Whether people with  
22 family history of cancer are more likely to be  
23 exposed to NDMA, that, you know, that side of the  
24 triangle, I'm not sure it's possible. But then  
25 again, for that confounder to introduce bias, it has

1 to -- it's dependent on how prevalent that  
2 confounder is in that population and how strong the  
3 confounder cancer and confounder NDMA relationship  
4 is. So just the absence of a confounder does not  
5 mean that necessarily the study is biased, if a  
6 confounder has to, you know, a number of criteria  
7 have to be met for that unmeasured confounder to  
8 actually -- as I have demonstrated in my table, to  
9 cause bias in the results.

10 But theoretically, it could be a  
11 potential confounder.

12 Q Okay. And Hidajat did not control for  
13 family history of cancer?

14 A No.

15 Q Correct?

16 A No.

17 Q Are you aware that infection with  
18 H. pylori is a potential risk factor for certain  
19 types of cancer?

20 A Again, it is a risk factor but it's  
21 not necessarily a confounder, because H. pylori is  
22 not really associated with NDMA exposure.

23 So not having H. pylori is not going  
24 to really bias the results because it's not a  
25 confounder. It's a risk factor. However, I don't

1 really see it as a major bias. Plus, again, it has  
2 to be differential between the two groups, even if  
3 it were a confounder.

4 So I don't -- yes, H. pylori was not  
5 measured. And it is -- it is a risk factor for  
6 mainly actually stomach cancer, but it is a risk  
7 factor of cancer. But it's not -- I don't believe  
8 it's necessarily a confounder because it doesn't  
9 meet the H. pylori NDMA length in the triangle, in  
10 the causal triangle.

11 Q Well, again, unless you control for  
12 it, you don't know if there's differential exposure  
13 between --

14 A Well, first -- first of all, it's not  
15 a confounder, so even if it's differential or not  
16 differential, because it's not a confounder, it  
17 should not really change the results. Smoking is a  
18 confounder. We talked about it because it satisfies  
19 the confounder definition, but H. pylori, you know,  
20 at first glance, it seems, like, oh, we should  
21 control for it because it's a risk factor for  
22 cancer. But it's not really -- it's not really  
23 associated with NDMA users. It's a relatively  
24 prevalent infection that many people have. So I  
25 don't really -- I don't really see how -- not

1 measuring H. pylori could really change the results.

2 Q What's the distinction that you see  
3 between smoking and infection with H. pylori, if  
4 smoking is a confounder but H. pylori infection is  
5 not?

6 A Smoking is a confounder because it's  
7 associated with cancer, and since it's probably  
8 associated with NDMA because these are -- rubber  
9 factory workers in the '60s and '70s and, you know,  
10 that -- that sort of profession. Especially back  
11 then, they were probably smokers. So it meets  
12 the -- the dual criteria of a confounder.

13 H. pylori only has one arrow to  
14 cancer, but it doesn't really have an arrow to NDMA  
15 in any way. It's not really associated with NDMA,  
16 so that's why it's only one arrow to cancer that  
17 makes it a risk factor and not a confounder.

18 Q Do you agree with me that if the  
19 members of the cohort from the Hidajat study who  
20 were classified -- who were classified by them as  
21 high NDMA were more likely to have H. pylori  
22 infection than the members of the cohort that were  
23 classified as low NDMA exposure, if that would skew  
24 the results?

25 MR. NIGH: Form objection.

1 THE WITNESS: No. Again, what you're  
2 talking about in terms of one group having more  
3 than the other is -- again, it's for  
4 confounders. So if you have a confounder  
5 that's showing up more in one group than the  
6 other, that confounder is probably biasing the  
7 results, and you have to do an analysis where  
8 you stratify by that confounder to make things  
9 clean.

10 H. pylori is not a confounder, and so  
11 even if one group had it more than the other,  
12 which we don't really believe is the case,  
13 would not really change, because it's --  
14 because it cannot change -- it's not affecting  
15 the exposure. It's only affecting the outcome.  
16 It wouldn't change the results, I don't believe  
17 so.

18 BY MR. GALLAGHER:

19 Q If there was a difference in the -- in  
20 the percentage of the cohort for high NDMA exposure  
21 that had H. pylori infection versus the percentage  
22 of the cohort classified as low NDMA that had  
23 H. pylori infection, you don't think that that would  
24 have any impact on --

25 A The --

1 MR. NIGH: Hold on. Hold on. He  
2 didn't finish his question.

3 Did you finish, Mr. Gallagher?

4 MR. GALLAGHER: I did, yeah.

5 MR. NIGH: Okay. Form objection.

6 THE COURT REPORTER: I didn't hear the  
7 end of the question, just the very end.

8 MR. GALLAGHER: Let me rephrase it.

9 BY MR. GALLAGHER:

10 Q Dr. Etminan, is it your opinion that  
11 if -- if there was a difference in the percentage of  
12 the cohort Hidajat classified as high NDMA exposure  
13 that had H. pylori infection versus the percentage  
14 of the cohort classified by Hidajat as low NDMA  
15 exposure that has H. pylori infection, that -- that  
16 would not have any impact on the results --

17 A I --

18 MR. NIGH: Hold on. Hold on. Hold  
19 on. I'm not sure if he's done.

20 BY MR. GALLAGHER:

21 Q That would not have any impact on the  
22 results of the study?

23 MR. NIGH: Form objection.

24 Go ahead, Doctor.

25 THE WITNESS: Well, I wouldn't say it

1 wouldn't have any impact. I would say it  
2 would -- it would affect maybe the precision,  
3 maybe a relative risk of say 5 to a 4. But it  
4 wouldn't reverse the direction of that -- that  
5 effect size. It wouldn't take a 4 to a .5,  
6 which confounders could -- could do.

7 This is just a risk factor. So  
8 absence of a risk factor could slightly change  
9 the precision, but it wouldn't change the  
10 direction of the -- of the effect size in  
11 Hidajat.

12 BY MR. GALLAGHER:

13 Q So you agree it could impact the  
14 observed hazard ratio?

15 A In the -- in the way that I just  
16 explained, yes.

17 Q So if we look at the table, you -- you  
18 say it could go theoretically from a hazard ratio of  
19 5 to a hazard ratios of 4 --

20 A It could -- it could, but it could be  
21 even lower because it has -- you know, there's such  
22 a huge sample size. But it's possible to affect  
23 precision of the -- of the effect size.

24 Q Okay. So if we look at your table,  
25 for stomach cancer, you're showing a hazard ratio



1 without a measured -- a measured confounder of  
2 1.782. Why couldn't it go from 1.72 to 1?

3 A No. I think -- I think you're just --  
4 I mean, that's -- that's speculation. I could also  
5 go to 1.4. I'm just making a general statement that  
6 because H. pylori is mainly a risk factor, provided  
7 that there is a huge differential in the -- in the  
8 level in the measurement of H. pylori between the  
9 high NDMA group versus the low NDMA group, there  
10 could be changing precision of the hazard ratio, but  
11 not a -- not a reversal of the direction of the  
12 hazard ratio.

13 Q Okay. Let's look at the Hidajat  
14 study, Exhibit 8.

15 THE VIDEOGRAPHER: Counsel, there's  
16 about 10 minutes left on this media unit.

17 MR. GALLAGHER: Okay. Thanks.

18 BY MR. GALLAGHER:

19 Q At Page 251, again, under "Exposure  
20 Assessments" --

21 MR. NIGH: I'm sorry. Why are we  
22 having to -- to break for a media? I haven't  
23 seen that with any other court reporter.

24 MR. GALLAGHER: It has happened in  
25 the -- in the other depositions.

1 MR. NIGH: The other -- you mean the  
2 other depositions using Veritext? Because I  
3 don't think that we need to be breaking to  
4 switch tapes. This is being done via Zoom, and  
5 it's being recorded via Zoom. I just don't  
6 understand why we would -- why we would break  
7 unnecessarily.

8 MR. GALLAGHER: Let me finish up for  
9 10 minutes, and then we can talk about that.

10 BY MR. GALLAGHER:

11 Q So looking under "Exposure  
12 Assessments" --

13 A Okay.

14 Q -- we had looked at this earlier, that  
15 the -- the measurements of NDMA are based on  
16 estimates from a database. And then further on,  
17 about halfway through this paragraph, it says,  
18 "Because only job information in 1967 was available,  
19 the primary analyses assumed all subjects remained  
20 in the same factory department, i.e., not  
21 necessarily in the same job, throughout their  
22 careers and were employed until retirement at age  
23 70, death or immigration."

24 Do you see that?

25 A Yeah.

1 Q So in addition to NDMA not actually  
2 being measured but being based on estimates from  
3 primarily German factories, in Hidajat, in this  
4 cohort, they didn't know what part of the factory  
5 these individuals were actually working in. They  
6 only had job information for one year, and they  
7 assumed that they stayed in the same department,  
8 right?

9 A Can I just have a few minutes to read  
10 this, if you don't mind?

11 Q Sure.

12 A I'm actually going to look at Hidajat  
13 at the very end in the discussion.

14 Q Sure, what --

15 A What was the exhibit number again for  
16 Hidajat?

17 Q Exhibit 8.

18 A Okay. Just one second, please.

19 Q Sure.

20 A Okay. So would you please repeat your  
21 question?

22 Q Sure.

23 So in addition to not actually  
24 measuring NDMA but relying on estimates that came  
25 primarily from measurements of German rubber

1 factories, because job information was only  
2 available for one year, 1967, the authors assumed  
3 that all the subjects stayed in the same factory  
4 department throughout their career. But they don't  
5 know if any of these workers moved -- moved around  
6 to various different departments?

7 A So, I mean, obviously, it's  
8 challenging to keep track of people -- people's  
9 occupation for 35 years. However, I think they took  
10 this issue seriously, and they do mention that they  
11 did sensitivity analyses looking at different  
12 duration of employment. And they mentioned that  
13 that didn't change the results.

14 Q So I understand that they did some  
15 sensitivity analyses around duration of employment,  
16 but they're still assuming that for the duration of  
17 employment, each subject is staying in the same  
18 factory department, right?

19 A Yeah. There is that assumption, but  
20 at least, you know, the sensitivity analysis of the  
21 different duration of employment, I believe is  
22 reassuring. But, yes, the assumption is that they  
23 did stay in that -- in that employment for -- for  
24 the amount of time.

25 Q So the sensitivity -- sensitivity

1 analysis around duration of employment, I understand  
2 that addresses the duration of employment, but that  
3 doesn't address this assumption that all the  
4 subjects are staying in the same department.

5 MR. NIGH: Form objection.

6 THE WITNESS: I mean, I'm not sure,  
7 honestly, whether different departments would  
8 have different exposure to NDMA over a 35-year  
9 period. But that -- that's -- I mean, that's  
10 just the nature of the study. And that's what  
11 they mention. Again, it -- the exposure of  
12 NDMA in the different departments for it to  
13 change a major cause and major bias in the  
14 study, it has to be quite big and only  
15 affecting one group as -- as we talked about  
16 with other types of carcinogens, to maintain --  
17 to change the direction of these results.

18 BY MR. GALLAGHER:

19 Q So if we go back to the first page of  
20 Hidajat, the right-hand column, bottom paragraph,  
21 the authors expressly say, "Exposures vary  
22 throughout the rubber manufacturing process."

23 A Exposures do vary, but my -- I think  
24 my point was exposure has to vary in one group, the  
25 high NDMA, for -- constantly for long periods, and

1     they don't have to -- and they shouldn't vary or  
2     stay static in the control group for a long period  
3     for this -- for this bias to be introduced.  If  
4     exposure -- varied exposure happens randomly through  
5     the population of these men in 35 years, again, that  
6     could maybe affect the precision a little bit then.  
7     But it shouldn't change the direction of the -- of  
8     the risk.

9           Q           But you're assuming the exposure to  
10    NDMA.  And what the -- the authors are admitting on  
11    Page 251 is they only have job information for one  
12    year.  So they're assuming that all subjects stayed  
13    in the same department.  They don't -- they don't  
14    know if they moved.

15                   MR. NIGH:  Form objection.

16    BY MR. GALLAGHER:

17           Q           Right?

18                   MR. NIGH:  Form objection.

19                   THE WITNESS:  They don't know if they  
20    moved, yeah.

21    BY MR. GALLAGHER:

22           Q           Okay.  And then additionally, if we go  
23    forward to Page 257, the right-hand column, the  
24    paragraph just above "Conclusions."  So in this  
25    paragraph, Hidajat is acknowledging several

1 limitations of -- of the study, right?

2 A Uh-huh.

3 Q Including the final sentence,  
4 "Finally, cross-contamination between departments  
5 cannot rule out the need for multi-pollutant  
6 models," right?

7 A Yeah.

8 Q "But given the high correlations  
9 between exposures, this requires different and  
10 complex statistical modeling with currently unknown  
11 validity in this context," right?

12 MR. NIGH: Form objection.

13 THE WITNESS: Right. Again, I go back  
14 to my -- the point that I have been repeating,  
15 the cross-contamination, for it to change the  
16 direction of the results, has to be  
17 differential only in one group. And I think  
18 they are just -- they are just listing one of  
19 the limitations that the study in general. But  
20 for this cross-contamination to change the  
21 consistent -- the increased risk of cancer in  
22 this study, it has to be a major differential  
23 factor. And I -- I believe that if it was, the  
24 authors would mention that in their limitations  
25 as well. Rather than just, you know,

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1 mentioning that there could be  
2 cross-contamination, they would maybe elaborate  
3 that the cross-contamination has affected these  
4 results because -- and they don't say that.

5 And I don't have any reason to believe there  
6 was a major differential contamination in one  
7 group versus the other group.

8 BY MR. GALLAGHER:

9 Q So -- but, again, this is impacting  
10 the actual measurement, so if we go back to the  
11 first page again, that paragraph we were just  
12 looking at, that says, "Exposures varied throughout  
13 the rubber manufacturing process." And then they go  
14 on to say, "Rubber dust tends to have the highest  
15 exposure in the beginning of the production process,  
16 particularly in handling of raw materials," right?

17 A Right.

18 Q And then, "Rubber fumes and  
19 N-nitrosamines are generated during the heating and  
20 curing processes," right?

21 A Right.

22 Q So Hidajat is basing their exposure to  
23 NDMA on the estimates of exposures in the various --  
24 in the various parts of the factory, right?

25 A Right.



1 MR. NIGH: Form objection.

2 BY MR. GALLAGHER:

3 Q They're not -- they're not actually  
4 measuring what the exposure to NDMA is, right?

5 A Well, I mean, I don't think that's --  
6 that's very, very difficult to do, so they are using  
7 the estimates. I think we have talked about this  
8 already.

9 Q Sure. And the limitation that they're  
10 acknowledging is potential for cross-contamination  
11 between departments. So if there was contamination  
12 of rubber dust into the department that was doing  
13 the heating and curing processes, that would have a  
14 huge impact on the assumption that the people in the  
15 heating and curing processes are the ones most  
16 highly exposed to N-nitrosamines and basing their  
17 conclusions of the hazard ratios off of that, right?

18 MR. NIGH: Form objection.

19 THE WITNESS: Again, that  
20 cross-contamination has to be sustained for  
21 duration of the followup and only in the  
22 NDMA -- high NDMA category, to cause the type  
23 of bias that you're talking about.

24 BY MR. GALLAGHER:

25 Q So that's what I'm saying, is the

1 cross-contamination would, because the high ND --  
2 they're classifying people in the cohort as either  
3 high NDMA or low NDMA based on where they're working  
4 in the -- in the factory; is that right?

5 MR. NIGH: Form objection.

6 BY MR. GALLAGHER:

7 Q In other words, that's their  
8 assumption. If there's actually cross-contamination  
9 into that department of, for example, rubber dust,  
10 just to use one, then their -- their assumptions --  
11 or their assignment of those individuals being high  
12 NDMA, it is directly impacting 100 percent of those  
13 people, differentially?

14 MR. NIGH: Form objection,  
15 argumentative.

16 THE WITNESS: Yeah. I don't -- I'm  
17 not sure if I agree with that. I mean, that's  
18 -- that's -- I think that's quite a stretch of  
19 what -- what could have happened. There is  
20 no -- I mean, I think you're just -- I mean,  
21 you're -- you're coming up with an assumption.  
22 But I don't -- I mean, even in this -- the  
23 limitations of their study, they don't mention  
24 such a huge limitation as a potential reason  
25 for the results that they found.

1 THE VIDEOGRAPHER: Counsel, there's  
2 about three minutes remaining.

3 MR. GALLAGHER: Okay. Why don't we go  
4 ahead and take a break?

5 MR. NIGH: I'm sorry. Are we taking a  
6 break because there's three minutes remaining  
7 on tape? Because we're -- we're ready to keep  
8 going. I mean, if this is going to be 10 hours  
9 of record time to have interruptions just  
10 because there's a certain amount of record, you  
11 know, tape time, this is not an interruption  
12 that we've had for any other court reporter.  
13 And I don't understand why we would have it  
14 here.

15 We have not had this for any of our  
16 depositions that the plaintiffs have taken of  
17 custodial depositions. And frankly, I think  
18 that this is not a reason to take a break. I  
19 want to us continue forward at this time.

20 Dr. Etminan, can you continue? Do you  
21 want to continue forward?

22 MR. GALLAGHER: Let's take a break.

23 MR. NIGH: No. No. No. We don't  
24 just take a break because -- because there's a  
25 limitation for -- for tapes for some reason

1           that we can't even get an explanation for.

2                       MR. GALLAGHER: Can we go off the  
3           record and discuss that?

4                       MR. NIGH: No. No. I want this on  
5           the record because I want to be arguing that if  
6           we're going to have 10 hours of record time,  
7           that we need to be getting through the  
8           deposition, not taking breaks just because  
9           there's a limitation in terms of tape time.  
10          This should not be -- this should not be a  
11          limitation for a Zoom deposition. We're ready  
12          to continue forward.

13                      THE VIDEOGRAPHER: Counsel, there's  
14          one minute.

15                      THE COURT REPORTER: Your court  
16          reporter needs a break.

17                      MR. NIGH: This is all coming out now  
18          in response to the tapes. I can tell. So you  
19          know we -- we need to be getting through this  
20          deposition, and now -- now, we're -- it is --  
21          this prompt was clearly because of tapes.  
22          That's what I heard. That's what started the  
23          whole thing. Now, it's sounding to me like  
24          other people are weighing in to try to save  
25          this response on the tapes. This happened

1 multiple times in other depositions, and that's  
2 exactly what I think the record is going to  
3 show here as well. We can go ahead and take a  
4 break.

5 THE VIDEOGRAPHER: The time is now  
6 1:57. This is the end of Media Number 2.  
7 We're going off the record.

8 (Whereupon, a short break was taken.)

9 THE VIDEOGRAPHER: The time is now  
10 11:13. This begins Media Unit Number 3. We're  
11 back on the record.

12 BY MR. GALLAGHER:

13 Q Okay. Dr. Etminan, looking at the  
14 Hidajat article again, Exhibit 8, it's the sentence  
15 starting on the first page, very bottom of the first  
16 page. It's only two words, "Due to," and then  
17 moving on to the beginning of the second page,  
18 Page 251, the author states, "Due to the complexity  
19 of exposure pattern and the numerous chemicals used  
20 in the rubber production process, this entangling  
21 exposure response associations between specific  
22 suspected carcinogens and cancer risks in this  
23 industry remains difficult."

24 Do you see that?

25 A Yes.

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1 Q And so the authors are acknowledging  
2 that while working in the rubber industry may be a  
3 significant risk of cancer, using occupational  
4 studies of the rubber industry to evaluate exposure  
5 response associations for a specific suspected  
6 carcinogen is something that's difficult to do,  
7 right?

8 MR. NIGH: Form objection.

9 THE WITNESS: Yes. That's what they  
10 say. But I think that part of -- part of what  
11 they're saying is to kind of strengthen their  
12 case as to why they did this study. I mean,  
13 this is in their introduction. But I mean, as  
14 a general statement, I -- I agree with -- with  
15 what is said.

16 BY MR. GALLAGHER:

17 Q Okay.

18 MR. GALLAGHER: If we can move on now  
19 to the next exhibit, are we at 10, Exhibit 10,  
20 the Lavecchia article?

21 THE COURT REPORTER: Can you spell  
22 that?

23 MR. GALLAGHER: Sure. Lavecchia,  
24 L-a-v-e-c-c-h-i-a.

25 THE COURT REPORTER: Thank you.

1 (Whereupon, Exhibit 10 was marked for  
2 Identification.)

3 THE WITNESS: I have it.

4 BY MR. GALLAGHER:

5 Q Okay. You relied on this study for  
6 your opinions related to gastric cancer; is that  
7 right?

8 A Yes. This is just the abstract,  
9 though. It's not the full PDF.

10 Q Right. Let me correct that.

11 MR. GALLAGHER: Okay. Can we go off  
12 the record for just one minute.

13 THE VIDEOGRAPHER: Sure. The time is  
14 now 11:17. We're going off the record.

15 (Whereupon, a discussion was held off  
16 the record.)

17 (Whereupon, Exhibit 11 was marked for  
18 Identification.)

19 THE VIDEOGRAPHER: The time is now  
20 11:19. We're back on the record.

21 BY MR. GALLAGHER:

22 Q Dr. Etminan --

23 MR. NIGH: Hold on. Before you ask --  
24 ask a question, I want to put on the record  
25 that we just had to take a three-minute break

1 to go off the record so that Counsel could  
2 substitute the "Nitrosamine Intake and Gastric  
3 Cancer Risk" abstract for the full study.

4 Do you disagree that's the reason we  
5 just went off the record, Mr. Gallagher?

6 MR. GALLAGHER: I don't understand  
7 your -- your -- all your troubles about taking  
8 breaks. I've never been in a deposition where  
9 we didn't take breaks for the court reporter,  
10 for the witness, for everybody, so --

11 MR. NIGH: I have been in many  
12 depositions where --

13 MR. GALLAGHER: -- we can take a  
14 break --

15 MR. NIGH: I have been in many  
16 depositions where we've -- especially expert  
17 depositions, where we have been able to go  
18 two hours at a time, and where the expert is  
19 at-will to be able to take the breaks.

20 At this point, the expert has not  
21 asked for a single one of these breaks that  
22 we've had at this point. And so, yes, I am  
23 concerned about excessive breaks when we have  
24 10 hours of record time. That leads to many  
25 hours of not record time.



1 MR. GALLAGHER: But --

2 MR. NIGH: No. You asked why I'm  
3 concerned. I am concerned. So here we just  
4 had another break that was not anything asked  
5 for by the witness. It was yet again you,  
6 Mr. Gallagher, here that just had the wrong  
7 document. All I wanted to do was put the  
8 reason for the break on the record. I asked if  
9 it was true. Do you agree that that was the  
10 reason for the break?

11 BY MR. GALLAGHER:

12 Q Dr. Etminan, do you have in front of  
13 you Exhibit 11?

14 A Yes.

15 Q And this is the Lavecchia article?

16 A Yes.

17 Q And you relied on this study in  
18 relation to your opinions related to NDMA and  
19 gastric cancer in this case, right?

20 A Right.

21 Q If you look at the abstract on the  
22 first page, the last sentence, you will see it says,  
23 "Limitations of exposure assessment and absence of  
24 information on other N-nitrosamines preclude,  
25 however, any definite assessment of the possible

1 role of exogenous N-nitrosamines in gastric  
2 carcinogenesis."

3 Do you see that?

4 A Yes.

5 Q And so the -- the authors are  
6 acknowledging that they can't make any definitive  
7 assessment of an association between exogenous  
8 N-nitrosamines and stomach cancer because of that  
9 limitation, right?

10 MR. NIGH: Form objection.

11 THE WITNESS: That's -- that's what  
12 they're suggesting, yes.

13 BY MR. GALLAGHER:

14 Q Okay. And they refer here to  
15 specifically exogenous N-nitrosamines, right?

16 A Yes.

17 Q Do you have an understanding of the  
18 distinction between endogenous NDMA and exogenous  
19 NDMA?

20 A To -- to -- you know, to certain  
21 levels, yes.

22 Q Okay. You haven't addressed anywhere  
23 in your report the -- the -- any potential impact of  
24 endogenous NDMA, have you?

25 MR. NIGH: Form objection.

1 THE WITNESS: No, because it's -- it's  
2 very difficult to quantify and ascertain  
3 endogenous NDMA exposure. I'm not familiar  
4 with any sort of robust gold standard, if you  
5 will, method to do it, because it's so complex.  
6 But then again back to what we discussed  
7 before, endogenous NDMA, you have to have a  
8 good reason why one group -- endogenous NDMA  
9 can be -- we can all be exposed to endogenous  
10 NDMA. It's a very complex sort of process to  
11 quantify.

12 But then, again, how can we actually  
13 say that one group in this study is exposed to  
14 more endogenous NDMA than the other? And  
15 that's -- and why -- and there's no reason to  
16 believe that's the case. So that's -- that's  
17 why I didn't discuss it in my report.

18 BY MR. GALLAGHER:

19 Q Okay. Why don't we turn to Page 472  
20 of this article?

21 So, Dr. Etminan, you say that there's  
22 a lot of complex factors that can influence  
23 endogenous NDMA; is that right?

24 A Yes.

25 Q Okay. And that's why you didn't

1 include it in your report or address it because it  
2 was complex?

3 A I mean, again, it's very hard to  
4 quantify and discuss it in most of the studies that  
5 I looked at it, and there's a lot of them. It  
6 wasn't really mentioned or measured, so for the  
7 whole host of reasons, that's why I mainly focus on  
8 exogenous NDMA.

9 MR. NIGH: And I object to the form of  
10 the last question.

11 BY MR. GALLAGHER:

12 Q Looking at the left-hand column here  
13 on Page 472, the sentence right above the last  
14 paragraph starting with, "However," the authors say,  
15 "However, we had no information on endogenous  
16 N-nitroso compound formation, which is influenced by  
17 gastric PH levels and other complex factors  
18 including microbial species in the mouth and  
19 stomach, N-nitrosation inhibitors besides subjective  
20 individual variation."

21 Do you see that?

22 A Yes.

23 Q So the -- the authors of the Lavecchia  
24 study acknowledge the potential issues with not  
25 having information on endogenous N-nitroso compound

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1 formation influenced by all these complex factors,  
2 right?

3 A I mean, they say that -- yeah, I mean,  
4 they say that's something that they probably  
5 won't -- would have liked to have had and address.  
6 But they don't go as far as saying that they think  
7 the results of their study could have been changed  
8 because of endogenous NDMA exposure.

9 And, again, I think it's because there  
10 is no reason to believe that the controls in the  
11 cases vary very differently coming from the same  
12 sort of population in terms of endogenous NDMA  
13 exposure.

14 Q But, again, unless you actually  
15 evaluate that, you don't know if there's a  
16 differential effect of --

17 A Yes -- for certain. Like, if you want  
18 to be certain whether there is a change in the  
19 effects, yes, you have to evaluate. But I am --  
20 again, I don't really know -- as far as I know,  
21 there are no sort of gold standard measurement tools  
22 to measure this in -- and incorporate it in an epi  
23 study.

24 THE COURT REPORTER: In a what study?

25 THE WITNESS: In an epidemiological

1 study.

2 MR. GALLAGHER: Can we mark as  
3 Exhibit 12 an article by Jakszyn,  
4 J-a-k-s-z-y-n, from 2006.

5 And, Doctor, let me know when it shows  
6 up and you have it.

7 THE WITNESS: Oh, sure. Sure.

8 (Whereupon, Exhibit 12 was marked for  
9 Identification.)

10 THE WITNESS: Okay. I got it.

11 BY MR. GALLAGHER:

12 Q You got it? Okay.

13 So the title of this article by  
14 Jakszyn is "Endogenous versus exogenous exposure to  
15 N-nitroso compounds and gastric cancer risk in the  
16 European Prospective Investigation into Cancer and  
17 Nutrition Study." Is that right?

18 A Yes.

19 Q So in this study, they did try to  
20 evaluate -- to measure and evaluate the potential  
21 impact of endogenous N-nitroso compounds, right?

22 A Yeah, seems like it.

23 Q Okay. And looking at the abstract, on  
24 the right-hand column -- of the top of the  
25 right-hand column of the first page, in this study,

1 they also were evaluating potential association of  
2 NDMA intake with risk of gastric cancer, right?

3 A Yes.

4 Q And you see about halfway down they  
5 say, "There was no association between NDMA intake  
6 and gastric cancer risk," right?

7 A Sorry. Where are you referring to?  
8 Oh. Yes, that's what they say.

9 Q Okay. And their observed hazard ratio  
10 for any potential association of NDMA intake and  
11 gastric cancer risk was exactly 1.00, right?

12 A Right.

13 Q And we had talked about a hazard ratio  
14 of 1 means there's no evidence of an association  
15 between the exposure and the risk, right?

16 A Right.

17 Q So in this study, when they were --  
18 they also evaluated endogenous N-nitroso compounds.  
19 That's abbreviated ENOC, right?

20 A Yes.

21 Q And there in the abstract they  
22 concluded -- or their data for endogenous N-nitroso  
23 compounds, the ENOC, was significantly associated  
24 with non-cardia cancer risk, right?

25 A Yes.

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1 Q If we turn to Table 1, which is on  
2 Page 1499.

3 A Uh-huh.

4 Q And this is providing a description of  
5 the sample included in the cohort. And do you see  
6 it's providing mean values for certain of the -- of  
7 the variables, including NDMA and endogenous  
8 N-nitroso compounds?

9 A Yeah.

10 Q The mean endogenous N-nitroso  
11 compounds in the -- in the study was 93.05  
12 micrograms per day, right?

13 MR. NIGH: Object to form.

14 THE WITNESS: How many --

15 BY MR. GALLAGHER:

16 Q And that would be 93,050 nanograms per  
17 day; is that right?

18 A Micrograms per nanograms.

19 THE COURT REPORTER: I'm sorry. Can  
20 you repeat that?

21 THE WITNESS: I was just saying  
22 micrograms per nanograms.

23 Can I just have a few minutes to read  
24 this, if you don't mind?

25



1 BY MR. GALLAGHER:

2 Q Sure, sure.

3 MR. GALLAGHER: So, Daniel, in our  
4 depositions when the witness needed a long time  
5 to review a document, we went off the record.  
6 My question is pretty simple.

7 MR. NIGH: We can go off the record.

8 MR. GALLAGHER: Okay. Off the record.

9 THE VIDEOGRAPHER: The time is now  
10 11:38. We're going off the record.

11 (Whereupon, a short break was taken.)

12 THE VIDEOGRAPHER: The time is now  
13 11:38. We're back on the record.

14 MR. GALLAGHER: Thank you. And can  
15 the court reporter read back the last question.

16 (Whereupon, the testimony was read  
17 back as requested.)

18 BY MR. GALLAGHER:

19 Q Dr. Etminan --

20 A Yes. So with respect to the lack  
21 of -- risk with exogenous NDMA, I think I have  
22 addressed this in my report at the follow-up of the  
23 study. It was only about 3 and a half years, which  
24 is inadequate for an exogenous carcinogen causing  
25 cancer, and also, I do mention that just from the

1 demographics of the study, which are mainly --

2 THE COURT REPORTER: Which are mainly  
3 what?

4 THE WITNESS: Elderly, older adults.

5 That they may have died before getting  
6 cancer, which usually has a longer sort of an  
7 onset. With respect to the 93,000 exogenous  
8 values, I -- the value seems quite high to me.  
9 And I don't -- I'm not familiar with the  
10 methodology that they used. And, again, I'm  
11 not saying that it's not the right methodology,  
12 but I just haven't seen any other study  
13 measuring endogenous NDMA as well.

14 BY MR. GALLAGHER:

15 Q Okay. In this study where they  
16 address endogenous and N-nitroso compounds, the mean  
17 endogenous N-nitroso compound in the -- in the study  
18 was 93,050 nanograms per day, right?

19 A Yes.

20 Q And if we go back to the abstract --

21 A Yeah.

22 Q -- the -- after presenting the hazard  
23 ratios for endogenous N-nitroso compounds, they go  
24 on to say, "Although the number of not infected  
25 cases is low, our data suggests a possible

1 interaction between ENOC and H. pylori infection,"  
2 right?

3 A Yes.

4 Q So they're seeing a possible  
5 interaction between an impact of endogenous  
6 N-nitroso compounds and infection with H. pylori?

7 MR. NIGH: Form objection.

8 BY MR. GALLAGHER:

9 Q Right?

10 A Yeah, the interaction basically means  
11 that the levels of the -- the risk of cancer with  
12 endogenous NDMA changes with levels of H. pylori, so  
13 I mean, they have H. pylori measured. So that's  
14 what they found. That's -- I mean, I agree with  
15 that.

16 Q Right. And so in this study where the  
17 authors accounted for endogenous N-nitroso compound  
18 and accounted for H. pylori infection, with respect  
19 to NDMA, the data showed no association between NDMA  
20 intake and gastric cancer, right?

21 A You mean --

22 THE COURT REPORTER: I'm sorry. You  
23 mean what?

24 THE WITNESS: No association with  
25 exogenous NDMA?

1 BY MR. GALLAGHER:

2 Q Yes, no association of exogenous NDMA  
3 intake and gastric cancer risk?

4 A Right. But I think I did address  
5 that, although those are restraints of the study,  
6 the limitation -- I mean, not showing an association  
7 is also dependent on other factors. One, you need  
8 an adequate follow up to be able to detect the  
9 cancer. Two, you need to control for deaths other  
10 than cancer, which may sort of lower the -- your  
11 sample size. So you have to address for that, which  
12 they haven't.

13 So I can't -- because they have other  
14 limitation -- methodological limitations, I can't  
15 just say, you know, there is no risk because they  
16 control for H. pylori and endogenous NDMA. There  
17 are other issues in the study design.

18 Q So with respect to the -- the time for  
19 follow up, it was sufficiently long since they  
20 identified a significant association of endogenous  
21 N-nitroso compound with non-cardia cancers, right?

22 MR. NIGH: Object to form.

23 THE WITNESS: Right. But I mean, the  
24 mechanism of cancer with exogenous, I mean,  
25 could take longer. And so you need to -- you

1           may need a longer follow up for that to be  
2           picked up.

3                   THE COURT REPORTER:   Could be what?

4                   THE WITNESS:   You may need longer  
5           follow up for the exogenous for -- for cancers  
6           from exogenous NDMA to be picked up or to be  
7           detected.

8                   THE COURT REPORTER:   Thank you.

9   BY MR. GALLAGHER:

10           Q           Why do you -- why do think it would  
11           take longer for an exogenous?

12           A           Because you have to be taking it  
13           constantly, and it has to be ingested and then  
14           absorbed systemically. And it's possible that the  
15           mechanism of carcinogenesis with exogenous NDMA  
16           may -- may be different.

17                   Just like when you have a drug that's  
18           culled in your system, it's -- it's getting absorbed  
19           more than if you're taking a pill every day that's  
20           only 20 percent absorbed. So the -- the constant  
21           exposure and the concentrations may be different.

22                   MR. NIGH:   Object to the form of the  
23           last question.

24   BY MR. GALLAGHER:

25           Q           So you're telling me that the time

1 frame of exposure to an -- to an exogenous  
2 carcinogen --

3 A I'm just saying that should -- it's  
4 possible that the -- sorry. I should have let you  
5 finish.

6 I'm just saying that the follow-up  
7 time for the exogenous NDMA to show cancer events  
8 where they could actually pick it up would have  
9 been -- could have been higher -- you know, longer  
10 than just the 3-year or 3-and-a-half-year follow up  
11 that they had.

12 Q And am I understanding right that  
13 you're saying the reason for that is because the  
14 time frame of exposure to an exogenous carcinogen  
15 is --

16 A Well, I mean, you don't --

17 THE COURT REPORTER: I'm sorry -- I'm  
18 sorry, Doctor. I'm not hearing the -- I'm not  
19 hearing the end of the questions, and  
20 therefore, I'm not having the full question on  
21 the record. If you could just take a deep  
22 breath and let Patrick finish his question  
23 before answering, I would appreciate it.

24 THE WITNESS: Okay.

25 MR. GALLAGHER: My apologies to the

1 court reporter and to Dr. Etminan.

2 BY MR. GALLAGHER:

3 Q So am I understanding properly, you're  
4 saying that the reason for that is because the time  
5 frame of exposure to an exogenous carcinogen is a  
6 significant factor in the potential for actual risk  
7 of cancer?

8 MR. NIGH: Object to the form.

9 THE WITNESS: Perhaps I would call it  
10 induction time, which means the time from being  
11 exposed from exogenous NDMA, which may take  
12 longer to the cancer process to occur and be  
13 diagnosed. Whereas, the endogenous, it's  
14 already in the system. Whereas, the exogenous,  
15 you need to be exposed to it, you know,  
16 constantly through -- orally or through the  
17 skin or through inhalation. So it may take  
18 longer for the NDMA to cause its carcinogenic  
19 effect for the cancer process.

20 BY MR. GALLAGHER:

21 Q Okay. You mentioned a few minutes ago  
22 and also in your report one aspect of -- of this  
23 study that you considered to be a material  
24 limitation is that it included in mostly older  
25 adults? Do I understand that right? And if you

1 want to look at Page 17 of your report, if you want  
2 to look at it is where you're discussing this.

3 A Yes.

4 Q Okay. So you recall that it's one of  
5 your criticisms of this -- of this article, right?

6 A Right.

7 Q If we look on Page 1498 of the  
8 article, just under "Material and Methods for  
9 Subjects," this cohort included women and men aged  
10 35 to 70 years, right? So their age range is 35 to  
11 70, right?

12 A Uh-huh.

13 Q And if we look at table 1, the mean  
14 age at recruitment was 59.2, right?

15 A Right. So -- sorry. Can I address --

16 Q Yes.

17 A Yes. So 60 is a year where, you know,  
18 they have cardiovascular disease. You could have  
19 diabetes. It's the year where these conditions  
20 these are prevalent. And deaths due to these  
21 conditions, the risk for -- for deaths due to  
22 diabetes and cardiovascular disease and other  
23 co-morbid condition is -- is also increasing.

24 So if patients die for these causes  
25 and not live -- live long enough to get cancer, that



1 is a bias that should be addressed, should have been  
2 addressed in this study. That's what I was  
3 referring to.

4 Q And then additionally, the -- so let  
5 me ask you this: Those other co-morbid conditions  
6 are factors from your perspective to be considered  
7 because they can impact -- could have impacted the  
8 results of this study?

9 A As you can see in Table 1, there's  
10 no -- there's no information given on -- as they  
11 have with the other variables, on the percentage  
12 and -- and the breakdown of other co-morbid  
13 conditions. I mean, if -- if the cases we're  
14 sicker, get more ill, because of these kind of  
15 conditions, could that have affected, you know dying  
16 of -- of cancer, including the ones that were --  
17 that died because of endogenous exposure. So I  
18 think that those are potential confounders that  
19 should have been adjusted for. And they were not.  
20 They were only adjusted for things like smoking and  
21 diet and physical activity, which are important, but  
22 there are other potential confounders which I think  
23 should have at least been mentioned as to why  
24 they --

25 THE COURT REPORTER: As to why they

1           were what?

2                       THE WITNESS:   They were not controlled  
3           for.

4   BY MR. GALLAGHER:

5           Q           Do you know what the age of the cohort  
6           was for the --

7                       THE COURT REPORTER:   For the what  
8           study?

9                       MR. GALLAGHER:   Hidajat.

10                      THE WITNESS:   I can look -- look it up  
11           right now.   I don't know off the top of my  
12           head.

13   BY MR. GALLAGHER:

14           Q           Okay.   So if we go to Exhibit 8,  
15           Page 251.

16           A           Uh-huh.

17           Q           Under "Material and Methods," the data  
18           is from male UK rubber factory workers aged 35 years  
19           or older as of 1 February 1967, right?

20           A           Right.

21           Q           And it's not -- perhaps not that  
22           surprising that in a cohort study, looking at risks  
23           of cancer, the cohort is including older  
24           individuals, right?

25           A           Right.   But -- but what Hidajat did

1 unlike -- none of the other studies that I have  
2 seen, is, if you look at Page 251 under "Statistical  
3 Methods," they did a special modeling technique  
4 called "Fine and Gray," which controls for death  
5 because it was such a long study with such a long  
6 follow up of say -- in 35 years. So people started  
7 at 35, but they would get to 50 and 60 and, you  
8 know -- in 10, 20 years, which is -- puts them at  
9 risk of other deaths, which as we've talked about,  
10 can bias the results if it's not -- if they're not  
11 accounted for. If they drop out of deaths other  
12 than cancer, then they don't get to get cancer. So  
13 they actually controlled for that with the  
14 Fine and Gray analysis.

15 Q And as people get older, one of the --  
16 one of the risks for getting cancer is getting  
17 older, right?

18 A Right.

19 Q Okay. You also criticize the Jakszyn  
20 study for not controlling for confounders such as  
21 history of stomach cancer, right?

22 A Yes.

23 Q If you look on Page 17 of your  
24 report --

25 A Right.

1           Q           -- that was one of your criticisms of  
2 the Jakszyn study.

3           A           Uh-huh.

4           Q           So the Hidajat study didn't control  
5 for confounders like history of stomach cancer,  
6 right?

7           A           You're right. They did not. But  
8 again, just the sheer size of the -- the sample  
9 size, the very long follow up, that -- that  
10 confounding factor, which theoretically is a  
11 confounder has to be disproportionately, you know,  
12 higher in the high NDMA group than the low NDMA  
13 group. And given this is a population-based study  
14 where to some accounts the rates are, you know,  
15 probably stable over time, or go up, you know, a  
16 little bit just like most European countries in the  
17 UK, I don't see why absence of that confounder would  
18 have made any difference. Whereas here with  
19 Jakszyn, it's a much smaller study, only a  
20 3-and-a-half-year follow up. So I'm -- and I  
21 believe it's -- I'm just looking at the sample size.  
22 I believe it's a smaller sample size --

23                   THE COURT REPORTER: I'm sorry. Than  
24 what?

25                   THE WITNESS: Than Hidajat. No. It's

1 a bigger study. It's a bigger study. It's a  
2 bigger study. But I believe it's got smaller  
3 number of cases than Hidajat does, because  
4 Hidajat followed for a long time. So there are  
5 more cases.

6 BY MR. GALLAGHER:

7 Q Okay. So you agree with me that  
8 the -- the Jakszyn study, which evaluated exogenous  
9 NDMA intake as well as endogenous N-nitroso  
10 compounds is a larger study than the Hidajat study?

11 A Number-wise, yes. Number-wise, it is.

12 MR. NIGH: Object to form.

13 BY MR. GALLAGHER:

14 Q And you criticized the Jakszyn study  
15 for not controlling for confounders like history of  
16 stomach cancer, right?

17 A Yes.

18 Q And the -- the Hidajat study also  
19 didn't control for confounders like history of  
20 stomach cancer, right?

21 A Yes.

22 Q And so that same criticism applies --

23 A It does.

24 THE COURT REPORTER: I'm sorry. Can  
25 you repeat that?

1 BY MR. GALLAGHER:

2 Q That same criticism of not controlling  
3 for confounders like a history of stomach cancer  
4 would be a criticism of any study that didn't  
5 account for that confounder?

6 A That's right. But keep in mind that  
7 I -- I sort of came up with my opinion on stomach  
8 cancer, not just on Hidajat alone and Jakszyn alone.  
9 It was the totality of evidence. And there are --

10 THE COURT REPORTER: I'm sorry. I'm  
11 sorry. What was that?

12 THE WITNESS: Lavecchia, the study we  
13 just talked about before this one, did control  
14 for stomach cancer history.

15 BY MR. GALLAGHER:

16 Q Okay. What does that mean to you -- I  
17 understand you didn't base your opinions solely on  
18 the Hidajat and the Jakszyn study. What does that  
19 mean to you, though, to be looking at the "totality  
20 of the evidence"?

21 A Totality of the evidence means  
22 biologically plausible evidence, which is mostly  
23 from animal studies; data from, mainly, Hidajat;  
24 from occupational studies; and data from dietary  
25 studies. And, again, it doesn't mean that every

1 single study is a perfect study that shows an  
2 increase in risk, and they don't have limitations.  
3 But the constellation of all of the evidence is what  
4 I weighted my opinion on.

5 Q Okay.

6 MR. GALLAGHER: Can we mark as the  
7 next exhibit, Exhibit 13, the Palli study.

8 (Whereupon, Exhibit 13 was marked for  
9 Identification.)

10 THE COURT REPORTER: Can you spell  
11 that?

12 MR. GALLAGHER: P-a-l-l-i.

13 THE COURT REPORTER: Thank you.

14 BY MR. GALLAGHER:

15 Q And, Dr. Etminan, you discuss this  
16 study at the top of Page 17 of your report.

17 A Okay.

18 Q Dr. Etminan, in this study, there  
19 was --

20 A Sorry. Sorry. Just give me one  
21 second to read this paper.

22 Q Sure.

23 A Okay. Go ahead.

24 Q This study did not find a  
25 statistically significant association between NDMA

1 and the risk of gastric cancer, right?

2 A It found an odd ratio of two that just  
3 missed statistical significance.

4 Q But it did miss statistical  
5 significance, right?

6 A Yes.

7 Q This study also reported a  
8 statistically significant increased risk for gastric  
9 cancer based on family history, right?

10 A Yes.

11 Q And family history for gastric cancer  
12 would be a known risk factor, right?

13 A It would be.

14 Is there a table that I should refer  
15 to or any numbers here?

16 Q Sure. You can look at -- we can look  
17 on Page 165.

18 A Sorry. Palli is Pages 1206 to --

19 Q Oh, sorry. It's the third page of the  
20 PDF, Page 165. There's Table 1.

21 A Okay.

22 Q Showing the family history and then in  
23 the left-hand column under "Results"?

24 A Uh-huh.

25 MR. NIGH: Are you following along on



1 Page 165 because I don't see a 165?

2 THE WITNESS: It's Page 1208.

3 MR. GALLAGHER: I think we need a  
4 different --

5 MS. APPEL: Yeah, I'm sorry --

6 MR. GALLAGHER: No worries.

7 MS. APPEL: (inaudible)

8 BY MR. GALLAGHER:

9 Q So we'll get there. But, Dr. Etminan,  
10 let's talk just -- let's talk about family history  
11 of gastric cancer.

12 Do you acknowledge that that is a  
13 known risk factor for a person to develop gastric  
14 cancer if they have a family history of gastric  
15 cancer, right?

16 A Yes.

17 Q And the -- the Hidajat study and the  
18 Lavecchia study, they didn't account for that?

19 A Yes.

20 Q -- as a factor -- as a factor, right?

21 A No.

22 MR. GALLAGHER: So Exhibit 14 should  
23 be coming. It's a Palli study.

24 (Whereupon, Exhibit 14 was marked for  
25 Identification.)

1 THE WITNESS: Okay.

2 BY MR. GALLAGHER:

3 Q Dr. Etminan, have you seen this  
4 article before?

5 A It's by Palli, so I may have seen it,  
6 but included the one that I -- included within my  
7 report, because it's pretty much from the same  
8 authors.

9 Q So can you explain that to me again?  
10 Have you seen this before or not?

11 A I may have, but I haven't included it  
12 in my report. I may have seen it in my search.

13 Q Okay. So you're not relying on  
14 this -- can you turn to your report, which is  
15 Exhibit 5, I think?

16 A Sorry.

17 Q Turn to your report, Exhibit 5, and on  
18 Page 17...

19 A Yes.

20 Q And you see at the top of Page 17, you  
21 refer to a population-based case controlled study  
22 conducted by Palli, right --

23 A Yes.

24 Q -- in Citation 43?

25 A Yes.

1 Q Can we go to Page 38 of your report?

2 A Yes.

3 Q And so the citation for 43 is to  
4 Palli, an article titled "Dietary Patterns, Nutrient  
5 Intake and Gastric Cancer in a High-Risk Area of  
6 Italy," right?

7 A Right.

8 Q And that citation is to the article  
9 that we were just looking at that's Exhibit 14,  
10 right?

11 A Right.

12 Q But you said you didn't rely on this  
13 for your report?

14 A Right. I thought there were two Palli  
15 studies that you showed me. The one Palli study  
16 that I cite in my report, I believe, is this one.  
17 Yes. It's this one because it's 382 gastric cancer  
18 cases, and that's what I have. So it's this one.

19 Q Okay.

20 A By Palli, Russo and Decarli.

21 Q I think we're confused because the  
22 article that you -- the Palli article you produced  
23 to us was the other one.

24 A Okay. Sorry.

25 Q Okay. Okay. So if we -- if we look

1 at Exhibit 14, on Page 165, the third page of the  
2 PDF, Table 1, it's presenting the data with respect  
3 to family history.

4 A Yes.

5 Q And in the description of the results,  
6 which is starting on the left-hand column of this  
7 same page, the authors state, "A positive family  
8 history for gastric cancer among parents or  
9 siblings, rural residence and lower social class  
10 were strongly associated with increased risk"?

11 A Yes.

12 Q So all of those -- the Palli study was  
13 able to determine that all of those factors were  
14 strongly associated with risk of gastric cancer,  
15 right?

16 A Those are risk factors, yes.

17 Q Okay. But there was no -- no  
18 statistically significant association between  
19 exogenous NDMA intake and gastric cancer from this  
20 study, right?

21 A No.

22 MR. GALLAGHER: Can we mark as  
23 Exhibit 15 the Loh paper, L-o-h.

24 (Whereupon, Exhibit 15 was marked for  
25 Identification.)

1 MR. GALLAGHER: Actually, I'll come  
2 back to that one. Can we mark the Kefzei paper  
3 and this will be Exhibit 16. K-e-f-z-e-i.

4 THE COURT REPORTER: K-e-f-z-e-i?

5 MR. GALLAGHER: Correct.

6 (Whereupon, Exhibit 16 was marked for  
7 Identification.)

8 THE WITNESS: I have it open.

9 BY MR. GALLAGHER:

10 Q Okay. And this is a paper that you  
11 refer to also on Page 17 of your report, right?

12 A Yes.

13 Q So the -- if we pull up Page 17 of  
14 your report that would be helpful.

15 A Yeah.

16 Q The paragraph on Kefzei, "The  
17 adjusted --" "The adjusted risk of gastric  
18 cancer" --

19 A I'm sorry. So -- I'm sorry. You're  
20 not on Loh then? You want to look at Kefzei?

21 Q Sorry. Yes.

22 A Okay. Let me get that. Let me get  
23 that. Okay.

24 Q So you say that, "The adjusted risk of  
25 gastric cancers with nitrosamine intake among men

1 was elevated by 6 percent, and you're basing that  
2 off of a hazard ratio of 1.06," right?

3 MR. NIGH: Objection.

4 BY MR. GALLAGHER:

5 Q And that's for one type of gastric  
6 cancer, right?

7 A Yes.

8 Q And then you acknowledge that this is  
9 not for other types of gastric cancer, gastric  
10 cardia, although the observed hazard ratio is 1.31,  
11 that did not --

12 THE COURT REPORTER: I'm sorry.

13 That's not very specific...

14 THE WITNESS: It did not reach  
15 statistical significance.

16 BY MR. GALLAGHER:

17 Q Did not reach statistical  
18 significance.

19 A Yeah.

20 Q You see that, right?

21 A Yes.

22 Q And then among women, the risk was  
23 also not elevated, right?

24 A Correct.

25 Q And you go on to say, "The lack of an

1 effect in this study," so you acknowledge that in  
2 this study, there's a lack of any association of  
3 exogenous NDMA with gastric cancer, right?

4 MR. NIGH: Object to form.

5 THE WITNESS: That's -- yes.

6 BY MR. GALLAGHER:

7 Q Okay. And you go on to try and -- one  
8 issue that you raised is a potential for  
9 misclassification of the diet questionnaire used in  
10 the study?

11 A Yes.

12 Q Right? That potential for  
13 misclassification that you're referring to is  
14 potential inaccurate reporting of -- of food intake  
15 by the subjects in the study, right?

16 A Correct.

17 Q Okay. Isn't that true of every  
18 dietary study that's based on a diet questionnaire?

19 A Yes, it could -- it could occur in any  
20 dietary study.

21 Q So the -- I guess what I want -- so  
22 regardless of whether the observed association is  
23 showing no association or showing some association,  
24 there is -- this is a criticism of dietary studies  
25 generally, the potential for inaccurate reporting

1 of -- of food intake, right?

2 A That's the one limitation of all  
3 dietary studies, right.

4 Q Okay. So -- let's move on then.

5 MR. GALLAGHER: Can we mark the Song  
6 study as -- are we at -- what exhibit number  
7 are we at?

8 (Whereupon, Exhibit 17 was marked for  
9 Identification.)

10 MR. GALLAGHER: So this will be  
11 Exhibit 17, the Song article.

12 BY MR. GALLAGHER:

13 Q Let me know when you have it,  
14 Dr. Etminan.

15 A I have it now.

16 Q Okay. So you agree with me that this  
17 is -- this article is reporting on a meta-analysis?

18 A That's correct.

19 Q Okay. Have you conducted a  
20 meta-analysis before?

21 A Yes.

22 Q Okay. And this is a meta-analysis of  
23 observational studies, right?

24 A Yes.

25 Q Is one of the limitations of a



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1 meta-analysis observational studies the potential  
2 for confounding variable?

3 A I mean -- yeah. I mean, that's a  
4 limitation of observational studies as well, yes.

5 Q So for any meta-analysis of  
6 observational studies, you would agree that residual  
7 confounding factors may distort the results?

8 A I mean, there is a potential,  
9 theoretically, yes.

10 Q So have you actually seen this article  
11 or just the abstract for it?

12 A No. I have seen -- I have -- I mean,  
13 I have looked at the numbers and the tables as well.

14 Q Okay. So if we look on -- do we have  
15 Page 9892?

16 A Okay.

17 Q So I guess, I think I asked this  
18 question somewhat generally although it applies to  
19 the -- certainly to the Song meta-analysis.

20 You would agree with me that  
21 measurement errors resulting from dietary  
22 questionnaires can impact the reliability of dietary  
23 studies, right?

24 MR. NIGH: Form objection.

25 THE WITNESS: Generally speaking, I

1 think we've -- we've talked about this, yes.

2 BY MR. GALLAGHER:

3 Q Okay. And dietary questionnaires -- a  
4 questionnaire doesn't ask subjects, how much NDMA  
5 did you eat -- the dietary, right?

6 A Yes. They ask about the dietary  
7 patterns of individuals, and then they convert the  
8 food groups to -- they convert the NDMA content in  
9 each food group based on the information they have  
10 on the amount of NDMA in each food category.

11 Q Okay. So it may ask, how much bacon  
12 do you eat, how much fish, how much fruit?

13 A That's right.

14 Q And then -- and then from there, the  
15 authors or the people conducting the study estimate  
16 NDMA intake for the subjects based on estimates for  
17 the amount of NDMA or any other compound in that  
18 particular food group, right?

19 A That's right.

20 Q And if those -- if those estimates are  
21 wrong, that also impacts the validity of the results  
22 from a dietary study?

23 A Also, I mean, potentially. We have  
24 talked about this. It's a limitation of dietary  
25 study.

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1 Q Okay. Let's go back to your report.  
2 We'll look at Page 18 and Section 10.2 at the bottom  
3 of the page.

4 A Okay.

5 Q It's is referring to colorectal  
6 cancer.

7 A Okay.

8 Q So for colorectal cancer, Hidajat  
9 didn't look at colorectal cancer right?

10 A No.

11 Q Didn't examine -- okay.

12 And the Straif occupational study did  
13 not find any specifically significant association,  
14 right?

15 A No.

16 Q Okay.

17 A Because I think it was just they  
18 didn't have enough cases because they -- I don't  
19 think they had enough number of events. But the  
20 answer to your question, is no.

21 They found a relative risk of  
22 one-and-a half, but because of the small number of  
23 events, it was very imprecise and not statistically  
24 significant.

25 Q What was imprecise?

1           A           The confidence interval. It was from  
2           .5 to 4.7, around the 1.5 estimate.

3           Q           Right. And so because the confidence  
4           interval includes 1.0, there's -- there's no  
5           evidence of an association, right?

6           A           No, I -- again, I think I talked about  
7           this earlier. It's -- the relative risk is 1.5  
8           based on very small number of events. And that 1.5  
9           comes with a very imprecise estimate. We cannot  
10          necessarily say that there is no increased risk. We  
11          can say that it's imprecise, and the results are  
12          basically -- I'm trying to find the right word.  
13          Uncertain, if you will.

14          Q           Okay.

15                   MR. GALLAGHER: Can we mark the Knekt  
16          paper? This will be Exhibit 18, I believe.

17                   (Whereupon, Exhibit 18 was marked for  
18          Identification.)

19                   THE COURT REPORTER: How do you spell  
20          that.

21                   MR. GALLAGHER: K-n-e-k-t.

22          BY MR. GALLAGHER:

23          Q           Let me know when it shows up.

24          A           Okay.

25          Q           So, Dr. Etminan, you rely on this

1 study with respect to your opinion -- your opinions  
2 with respect to colorectal cancer?

3 A Right.

4 Q But you criticize the study with  
5 respect to your opinion for gastric cancer. Do you  
6 recall that?

7 MR. NIGH: Object to form.

8 BY MR. GALLAGHER:

9 Q And feel free to refer to Pages 17 and  
10 19 of -- of your report, which is Exhibit 5.

11 A Yes, just give me a second.

12 So my criticism was, again, for, I  
13 believe, competing events -- lack of control for  
14 competing events. Patients end up dying before  
15 getting stomach cancer. You could argue it's -- you  
16 know, it could be --

17 THE COURT REPORTER: I'm sorry. I'm  
18 sorry. Can you speak up and repeat that,  
19 please?

20 THE WITNESS: So my criticism was a  
21 lack of controlling for competing events for --  
22 for death due to other causes. If patients  
23 died earlier, they -- you know, some patients  
24 could have died early and not get stomach  
25 cancer. One could argue it's the same -- it

1 could be the same for colorectal cancer  
2 patients. But it's also possible that those  
3 patients were followed up over longer periods.  
4 We don't know.

5 But my other criticism is the smaller  
6 number of cases in the -- for stomach cancer is  
7 68 in the -- for the stomach cancer cases, and  
8 for colorectal cancer, it's 73. 68 versus --  
9 I'm reading that off of Table 1 -- 73. So  
10 those -- those five extra cases could -- you  
11 know, could change the results. So that's what  
12 I based my opinion on.

13 Because -- I'm sorry. If I could just  
14 add because the -- the upper bound --

15 THE COURT REPORTER: I'm sorry.  
16 Doctor, I'm sorry. You're speaking with your  
17 hand over your mouth, and I'm not understanding  
18 you.

19 THE WITNESS: Okay. The upper bound  
20 confidence interval for stomach cancer is 1.51,  
21 so it's very wide, suggestive of a small number  
22 of cases. Whereas for colorectal cancer, it's  
23 higher. And it's significant, so the  
24 difference of these five cases could  
25 potentially -- I mean, it is possible that

1           these extra five cases made a difference, but  
2           we don't know.

3       BY MR. GALLAGHER:

4           Q           Well, for gastric cancer, the lower  
5           bound is 0.37, right?

6           A           Yes, it's .037. I'm not arguing about  
7           the magnitude. It's -- it goes from very low to  
8           relatively high. I'm just saying that this very  
9           wide bound is suggestive of a small number of  
10          events. And so this study may not have had enough  
11          events to show a more precise estimate for stomach  
12          cancer.

13          Q           Well, the lower bounds -- let's talk  
14          for a minute about what it would mean for the hazard  
15          ratio to be 0.37. What would that mean to you?

16          A           The 3.7 hazard ratio is -- it means  
17          that it's -- it's a protective event.

18          Q           So if the -- okay. It would be  
19          protective.

20                       In your report -- Dr. Etminan, do you  
21          have a phone with you or anything else?

22          A           Yes.

23          Q           I guess I would ask that you -- okay.  
24          You're not receiving communications from anybody --

25          A           No. No. No.

1 Q -- on the phone are you?

2 A No. My phone was right behind my  
3 laptop.

4 Q Okay. Yes, please keep that set to  
5 the side.

6 So in your report on page Exhibit 17,  
7 you criticize the Knekt study possibly having  
8 imprecision of dietary questionnaires for  
9 quantifying NDMA from different food groups, right?

10 A Right.

11 Q And then carrying over onto Page 18,  
12 "This imprecision might have led to  
13 misclassification of the true NDMA effects with  
14 respect to cancer and might have led to null  
15 results."

16 Do you see that?

17 A Yes.

18 Q When you're saying that, that  
19 imprecision of the dietary questionnaires, would  
20 apply equally to the data with respect to colorectal  
21 cancer, right?

22 MR. NIGH: Object to form.

23 THE WITNESS: Not if they're not the  
24 same people answering the question. I mean,  
25 if -- if they -- if the stomach cancer cases,



1           let's say -- and we don't know this, but I'm  
2           just answering your question. If the stomach  
3           cancer cases give more imprecise answering than  
4           the colorectal cancer cases, then they would  
5           have more imprecise estimate in the results  
6           because they're not the same patients.

7       BY MR. GALLAGHER:

8           Q           Okay. Would you expect there to be a  
9           difference in the imprecision of -- well, I guess a  
10          couple of questions.

11                    One, when you're talking about that,  
12          you're talking about imprecision of the actual  
13          answers to the dietary questionnaire, what foods --

14          A           Right. So you have imprecision on  
15          what's a measurement error from the -- the study  
16          population, and then you -- I mean, you may have --  
17          in all studies of this nature, you could have an  
18          imprecision in recording the data.

19                    I'm just saying because they're --  
20          they're not the same patients. You can't assume  
21          that the same thing would happen to cancer -- happen  
22          to colorectal cancer than happen to stomach cancer  
23          cases or vice versa.

24          Q           Okay. Would you expect there to be a  
25          difference in the manner in which the foods -- the

1 dietary questionnaires answered by individuals who  
2 end up with stomach cancer versus individuals who  
3 end up with colorectal cancer?

4 A Generally speaking, no. But again --  
5 let me just check one thing.

6 Q Dr. Etminan --

7 A Generally speaking, no.

8 Q Okay. And then there's an additional  
9 possibility for error -- additional possibility for  
10 imprecision in quantifying the NDMA. And that's if  
11 the estimate that the authors used for the amount of  
12 NDMA in any specific food group, if that's  
13 incorrect, then that's going to lead to  
14 imprecision -- imprecision also. And that  
15 imprecision would apply equally with respect to  
16 stomach cancer and colorectal cancer, right?

17 A Yes.

18 Q Okay. When you make the statement  
19 here that the imprecision might have led to  
20 misclassification of the true NDMA effect with  
21 respect to cancer, you're assuming that there's an  
22 effect of NDMA on the cancer, right?

23 MR. NIGH: Object to form.

24 THE WITNESS: I'm assuming -- again,  
25 because of the smaller number of cases and the

1 upper bound confidence interval, the number in  
2 the results we see is -- basically, we don't  
3 know. And so it is possible.

4 BY MR. GALLAGHER:

5 Q But what the data is -- okay.

6 THE VIDEOGRAPHER: Counsel, there's  
7 about 10 minutes left on this video unit.

8 MR. GALLAGHER: Okay. I will finish  
9 this up, and then we can take a break for  
10 lunch.

11 Can we mark the -- we already marked  
12 the Loh study.

13 THE WITNESS: What's the exhibit  
14 number on Loh?

15 MR. GALLAGHER: Exhibit 15.

16 THE WITNESS: Okay.

17 BY MR. GALLAGHER:

18 Q And I think this is similar to the  
19 Knekt paper that we were just talking about, you --  
20 you criticize the Loh study with respect to gastric  
21 cancer. But then you rely on it for your opinions  
22 with respect to colorectal cancer. Do you recall  
23 that?

24 MR. NIGH: Object to form,  
25 mischaracterizes evidence.

1 THE WITNESS: I don't recall. I don't  
2 recall.

3 BY MR. GALLAGHER:

4 Q Okay. If you want to look at your  
5 report on Page 17 and on Page 19?

6 A Okay.

7 Q So -- and maybe if we pull up Page 17,  
8 the second paragraph.

9 A Yes.

10 Q Okay. So you refer to imprecise  
11 estimates of the risk. Why do you consider them to  
12 be imprecise?

13 A Of the 1.13? Because -- because your  
14 upper bound when the -- when the upper bound is  
15 clinically can -- shows a clinically significant  
16 risk and you have an end point interval which goes  
17 from .81 and the relative risk is 1.13. So it's,  
18 you know, it's not large, but it's a 13 percent  
19 increase. That means, it's -- it's an imprecise  
20 estimate. And then if you look at Loh's number of  
21 gastric cancers, that also kind of brings the  
22 message home, because they only had, I believe,  
23 55 -- I'm just trying to look at it -- what was Loh  
24 number again, sorry, the exhibit number?

25 Q 15, Exhibit 15.

1           A           They only had 64 cases where, you  
2 know, in other cancers -- like others in the "other  
3 cancer" category, you have 1,462 cases. For  
4 stomach, you only have 64. So that's why I said  
5 it's imprecise.

6           Q           So would you -- you're referring to  
7 the upper bound and the lower bound?

8           A           Yeah.

9           Q           And you said where the upper bound is  
10 showing a potential association that that's what  
11 you're considering to be imprecise --

12          A           I would say -- I wouldn't say  
13 association. It shows a risk of 1.57, which is  
14 clinically significant. If it was 1.2, then one  
15 would say well, even the upper bound of 1.2 is not  
16 that big of a deal. But 1.57 makes it significant.

17          Q           How are you -- how are you deciding  
18 that 1.2 might not be clinically significant but  
19 1.57 might be clinically significant?

20          A           I mean, usually anything below 1.5, we  
21 think that -- and closer to 1 is significant of no  
22 risk. And the higher, from 1.5 to even higher, is  
23 suggestive of -- if it's the upper bound and it's  
24 imprecise, I would say, if it's above an increase in  
25 risk that's imprecise, that needs to be looked into,

1 or inconclusive basically.

2 Q Okay. You would agree with me that if  
3 there is no association between an exposure and a  
4 risk, you would expect the observed relative risk to  
5 be close to 1, right?

6 MR. NIGH: Object to form.

7 THE WITNESS: I don't -- I don't want  
8 a say yes. That's a very, very general  
9 statement. There are large -- very large  
10 studies done with relative risks of 1.15 or  
11 1.16 that is -- where the results have been  
12 taken seriously. So I don't want to say yes as  
13 a general statement.

14 THE VIDEOGRAPHER: Counsel, there's  
15 about 3 minutes remaining.

16 MR. GALLAGHER: Okay. Let me finish  
17 this up, and I'll take a break.

18 BY MR. GALLAGHER:

19 Q I guess my question was slightly  
20 different. If there is no association between an  
21 exposure and a risk, start from that assumption, you  
22 would expect the observed -- the observed relative  
23 risk to be close to 1, right?

24 MR. NIGH: Object to form.

25 THE WITNESS: If you knew -- if you

1           knew there isn't an association?

2       BY MR. GALLAGHER:

3           Q           You know there is not an association  
4       between the exposure and the risk --

5           A           Right. Right. I want -- right. So  
6       the relative risk has to be close to 1 and the  
7       upper -- the -- the confidence intervals also have  
8       to be precise enough to exclude a risk, right?

9                       So -- so if you tell me there is a  
10      relative risk of 1.2 with a confidence interval of  
11      1.9 to 1.3, that -- that would tell me that, yes,  
12      there's probably no risk associated. But with an  
13      upper bound of 1.57, I would like -- you know, I'm  
14      more comfortable saying this is an inconclusive  
15      study rather than a no risk or a negative study.

16          Q           But you agree that the data, the  
17      confidence interval is -- is going to or can include  
18      both below 1 and above 1 if there's no association?  
19      In fact, you might expect that?

20                      MR. NIGH: Object to form.

21      BY MR. GALLAGHER:

22          Q           Correct?

23          A           Well, precision, if I wanted -- if I  
24      want to decide on risk or no risk, precision is also  
25      important because you could have -- again, as I

1 think you mentioned, you could have a low relative  
2 risk that has a huge confidence interval. Actually,  
3 that -- that is more inconclusive than negative. If  
4 it's a relative risk close to 1 with a very tight  
5 confidence interval also close to 1 or below 1.5 for  
6 the upper limits, that is -- yes, that -- I'm more  
7 confident in that case that there is no risk.

8 BY MR. GALLAGHER:

9 Q Where are you coming up with this --  
10 this limit of 1.5?

11 A 1.5 or higher, not just 1.5. 1.5 or  
12 higher.

13 Because it's -- it's technically a  
14 15 percent increase that -- that is included in that  
15 interval. And one should, you know, do a further  
16 investigation to further look at that. I don't  
17 think it's -- it's high enough to warrant further  
18 investigation with a bigger study, you know, higher  
19 number of cases. It is not a definitive negative  
20 with those numbers.

21 MR. GALLAGHER: We can go off the  
22 record now.

23 THE VIDEOGRAPHER: The time is now  
24 12:49. This ends Media Unit Number 3. We're  
25 going off the record.



1 (Whereupon, a lunch recess was taken.)

2 THE VIDEOGRAPHER: The time is now  
3 1:30. This begins Media Unit Number 4. We're  
4 back on the record.

5 BY MR. GALLAGHER:

6 Q Welcome back, Dr. Etminan.

7 A Thank you.

8 Q Did you have a good lunch?

9 A Not bad.

10 Q Excellent. In part of your report,  
11 Dr. Etminan, you go through a Bradford Hill  
12 analysis?

13 A Yes.

14 Q Is a Bradford Hill analysis something  
15 that you do in your professional capacity outside of  
16 serving as an expert for litigation?

17 A I mean, I use the criteria set by  
18 Bradford Hill to when I'm looking for -- or asking  
19 questions as part of my research on whether Drug A  
20 causes, you know, outcome Y, because I feel like it  
21 is relatively complete, and it has a lot of the sort  
22 of variables that one needs to consider when  
23 deciding on a cause --

24 THE COURT REPORTER: On a cause of  
25 what?

1 THE WITNESS: Causal question.

2 THE COURT REPORTER: Thank you.

3 BY MR. GALLAGHER:

4 Q Have you published papers that present  
5 the Bradford Hill analysis?

6 A I can't remember off the top of my  
7 head, but most of my papers are original research,  
8 which means I am -- I am not really asking a causal  
9 question based on the available evidence. I'm  
10 asking a causal question, say, on the drug that's  
11 never been asked before. So, you know, the  
12 Bradford Hill doesn't necessarily apply to those  
13 types of questions. But I have used it as part of  
14 my research when I'm reviewing a topic.

15 Q So when you say most of your  
16 research -- I will ask you a new question. Strike  
17 that.

18 When you say most of your research is  
19 the type of research that Bradford Hill wouldn't  
20 apply to, why is that?

21 A Because Bradford Hill, again, is a  
22 method used to establish causality on questions  
23 where there is evidence already. And so one uses  
24 this criteria with that evidence to see whether  
25 there's a causal link between that drug and that

1 outcome.

2 If I'm doing an original study where  
3 no one has looked at the question, you know, before,  
4 or there isn't a lot of evidence and I am the  
5 actual -- the only person or the very few people who  
6 are actually trying to answer the question, then the  
7 Bradford Hill doesn't really apply to these types of  
8 original research studies.

9 MR. GALLAGHER: I'd like to mark as  
10 the next exhibit, Exhibit 19, an article by  
11 Bradford Hill that you cited in your report.  
12 Let me know when it shows up.

13 (Whereupon, Exhibit 19 was marked for  
14 Identification.)

15 THE WITNESS: Okay. Oh, sorry. I'm  
16 still -- I'm still waiting.

17 BY MR. GALLAGHER:

18 Q Okay. Did it just pop up now?

19 A It did now, yeah.

20 Q Okay. If we can share the first page  
21 of this article. So this is an article by a  
22 professor from the University of London,  
23 Sir Austin Bradford Hill, right?

24 A Right.

25 Q And the title of the article is, "The

1 Environment and Disease Association or Causation,"  
2 right?

3 A Right.

4 Q And this is -- the article  
5 originally -- this is a republication of an article  
6 first published in 1965 where Sir Bradford Hill lays  
7 out the factors that he feels are appropriate to  
8 evaluate in assessing the causation question, right?

9 MR. NIGH: Object to form.

10 THE WITNESS: Yes.

11 BY MR. GALLAGHER:

12 Q You agree with me that association is  
13 different from causation, right?

14 A Generally speaking, all the causations  
15 are associations, but not all associations are  
16 causations.

17 Q All right. Can you say that again?

18 A All causations are associations, but  
19 the reverse is not true; so not all associations are  
20 causations.

21 Q Okay. I just wanted to make sure that  
22 I understood you properly.

23 So those are -- there can be  
24 associations that are observed where there's not a  
25 causal connection between the exposure and the

1 result?

2 A Yes.

3 Q Correct?

4 A That's called an association, yeah.

5 Q And the numbers -- or the variables  
6 that we have been discussing today, like relative  
7 risk and hazard ratio, those are a measure of  
8 association, right?

9 A No, those are measures -- or they are  
10 measures of effect. So you could have an effect of,  
11 let's say, a hazard ratio of 10 that's -- from a  
12 study that only shows an association, or it can show  
13 a hazard ratio of 10 from a study that shows  
14 causation.

15 So the hazard ratio and the rate ratio  
16 is mainly the effect size, the -- the -- the  
17 magnitude of the effect. Whether it's an  
18 association or a causation comes to, you know, the  
19 variables discussed by Bradford Hill and also, you  
20 know, presence of confounding and all the other  
21 principals that we've discussed.

22 Q Okay. And when you say it's a measure  
23 of the magnitude of the effect, it's -- the hazard  
24 ratio, as a variable being measured, is not of  
25 itself measuring causation. You have to go through

1 the...

2 A One of the criteria set by  
3 Bradford Hill and also --

4 THE COURT REPORTER: And also the  
5 what?

6 THE WITNESS: There has to be an  
7 effect from the exposure to classify whether  
8 it's a -- you know, if it's -- if a drug is --  
9 has a relative risk of 1 with respect on  
10 outcome, that drug is not causing that outcome.  
11 So that -- that magnitude has to be more than  
12 1.

13 But on top of that, that -- you know,  
14 that magnitude that's greater than 1 also has  
15 to have other criteria that Bradford Hill has  
16 talked about to be classified as a causal link.

17 BY MR. GALLAGHER:

18 Q Okay. Looking at the -- the first  
19 page on the right-hand column going through the nine  
20 factors that Bradford Hill lists, the first factor  
21 he lists is strength. Do you see that?

22 A Yes.

23 Q And so is this what -- what you're  
24 referring to in terms of the greater the magnitude  
25 of the association, the more evidence there is that

1 the association may actually be a causal  
2 relationship?

3 A Right. It's one of the criteria, yes.

4 Q It's just one of the criteria. Okay.

5 And Sir Bradford Hill gives an example  
6 of an association -- occupations of patients with  
7 scrotal cancer versus occupations of patients  
8 presenting with other diseases. And the mortality  
9 of chimney sweeps --

10 THE COURT REPORTER: I'm sorry. The  
11 mortality of what?

12 BY MR. GALLAGHER:

13 Q Of chimney sweeps from scrotal cancer  
14 was some 200 times that of workers who were not  
15 specially exposed to tar or mineral oils. Do you  
16 see that?

17 A Yes.

18 Q And so that's an example of a strong  
19 association where the magnitude of the observed  
20 association is high enough that it's much more  
21 suggestive of a causal relationship, right?

22 A Right.

23 Q And so if we're looking at hazard  
24 ratios that are perhaps above -- the observed hazard  
25 ratio is above 1, it's like 1.5, that's less

1 suggestive of a causal relationship without --  
2 without more, right?

3 MR. NIGH: Object to form.

4 THE WITNESS: Again, I disagree. It's  
5 not a -- it's not a one-size fit all sort of  
6 assumption to make. A hazard ratio of 1.5 that  
7 meets the other criteria set by Bradford Hill  
8 and also other -- it also satisfies, you know,  
9 minimal bias in terms of a study having a  
10 minimal amount of biases. One can still infer  
11 that there is a causal link. I mean, the 200  
12 times is a very rare example that he mentions,  
13 and I have never seen any drug or any exposure  
14 to having 200 times of the risk. That's an  
15 extreme.

16 It's a good teaching example, but in  
17 real life, I have never seen anything that can  
18 cause that much of a magnitude. So that's  
19 really not a -- that level should not really be  
20 set as a -- as a sort of standard of effect  
21 sizes for causality.

22 BY MR. GALLAGHER:

23 Q Sure. I mean, additional --  
24 Sir Bradford Hill goes on to provide an additional  
25 example of the death rate from cancer of the lung in



1 cigarette smokers as nine to ten times the rate of  
2 nonsmokers. And the death rate in heavy smokers is  
3 20 to 30 times as great, right?

4 A Uh-huh.

5 Q So that's just another example.

6 I guess my only question is -- is to  
7 understand how this factor is evaluated. If you  
8 have a relative risk -- observed relative risk of  
9 1.5, that is for this factor not as suggestive for a  
10 causal relationship as if the relative risk is like  
11 for cigarette smoking, 10 times or 20 to 30 times?

12 MR. NIGH: Object to form.

13 THE WITNESS: No. I wouldn't say  
14 that, you can't -- if it's 1.5 and, again, all  
15 the other criteria have been met, I don't think  
16 you can say it's -- it's not causal. We can  
17 say that a relative risk of 10, again, with  
18 everything being checked in and checked out  
19 with all the other criteria, just talking about  
20 the effect size, a relative risk of 10 is -- is  
21 suggestive of a stronger causal link than the  
22 1.5. But you can disregard the 1.5 risk,  
23 especially if you're making a population,  
24 because the 1.5 risk of a disease in the large  
25 population can lead to -- even though it's a

1           small number, but it can -- because the  
2           population is large, it can lead to a  
3           significant number of cases. So I think,  
4           again, you can't generalize it in that fashion.

5       BY MR. GALLAGHER:

6           Q           So is what you're saying is you  
7           essentially don't -- from your perspective, you  
8           don't apply this factor of evaluating the strength  
9           of the association because there -- you know, there  
10          can be an association no matter what the relative --  
11          observed relative risk is?

12                   MR. NIGH: Object to the form,  
13           mischaracterizes testimony.

14                   THE WITNESS: No. I definitely look  
15           at it -- I definitely look at event sizes, but  
16           I don't have a threshold to say, you know, if  
17           it's not close to 200, then I'm not going to  
18           consider it as a causal link. I would say  
19           again, and this is -- a lot of scientists,  
20           epidemiologists, use a relative risk of 2.  
21           Some use 1.5. I would say anything greater  
22           than 1.5 that satisfies the other criteria  
23           would be -- or higher, would be -- would  
24           satisfy this effect size criteria of  
25           Bradford Hill.

1 BY MR. GALLAGHER:

2 Q Okay. But you would agree with me  
3 that if the observed relative risk is 1.5, that you  
4 would want more additional information from the  
5 other factors to infer causal relationship than  
6 perhaps you would insist on if the observed relative  
7 risk was 20 or 200?

8 A Again, the other -- the other factors  
9 are independent of the effect size. I mean, you can  
10 have an effect size of 100, but if the other factors  
11 do not satisfy -- are not satisfied, just because  
12 you have an effect size of 200, you cannot say  
13 there's a causal link because the temporality may  
14 not be there. The analogy may not be there. The  
15 biases could be there.

16 So again, the magnitude of effect size  
17 has to be there, but there is no set standard. And  
18 it doesn't -- it's not the only variable that we  
19 look at.

20 Q Okay. Moving on to on Page 33, the  
21 right-hand column, the second Bradford Hill factor  
22 is consistency?

23 A Yes.

24 Q And under "Consistency" for  
25 Bradford Hill --beneath that in the paragraph, if we

1 can include the -- and the paragraph right below  
2 that as well.

3 So Sir Bradford Hill says that, "This  
4 requirement may be of special importance for those  
5 rare hazards singled out in the section's terms of  
6 reference," right?

7 Do you see that?

8 A Uh-huh.

9 Q What is your understanding of how  
10 the -- this factor of consistency is applied?

11 A Again, I think Bradford Hill, as you  
12 have it on -- on the screen, he mentions is -- he  
13 means by consistency, has it been repeated in  
14 different persons, in different places,  
15 circumstances. So is it perhaps consistent with  
16 being observed or seen?

17 And so that's -- that's what I also  
18 take -- take it to mean, that is this -- is this  
19 effect that I'm seeing, has it been seen in other  
20 settings or in other studies. It doesn't mean that  
21 it has to be observed in every single study, but is  
22 it -- is it just a one-time event, or is it being  
23 observed in other settings as well.

24 Q Okay. And so that would be like, for  
25 example, there's -- where there's multiple studies

1 designed in different ways that are showing -- that  
2 are showing the same relationship, right?

3 A Yes. And I also would include even  
4 animal studies as well, because they also -- I mean,  
5 I know that's far more biologic plausibility. But  
6 if there is studies repeating -- like, repeatedly  
7 showing that there is cancer within carcinogenic  
8 animal studies, I think that should also be part of  
9 consistency as well.

10 Q Okay. And if you see over on Page 34,  
11 the next page, the top -- the left-hand column at  
12 the top, again discussing consistency,  
13 Sir Bradford Hill says, "I would, myself, put a good  
14 deal of weight upon similar results reached in quite  
15 different ways, e.g., prospectively and  
16 retrospectively."

17 Do you see that?

18 A Yeah.

19 Q And so from -- from his perspective,  
20 looking at studies, both studies that may be looking  
21 retrospectively but also studies that are being done  
22 prospectively, is significant to him in terms of  
23 determining whether an association -- whether this  
24 factor of consistency is met, right?

25 MR. NIGH: Object to form.

1 THE WITNESS: Yeah.

2 BY MR. GALLAGHER:

3 Q The third factor over on the  
4 right-hand column of -- of this Page 34,  
5 specificity?

6 A Yes.

7 Q And this factor -- and this factor is  
8 looking at whether there's a specific association  
9 between the -- disease and an exposure; is that  
10 right?

11 A Yes.

12 Q And then at the bottom of Page 34, the  
13 fourth factor is temporality. So this is a question  
14 of -- of timing, right?

15 A Yes.

16 Q Does the -- does the exposure come  
17 before the outcome, right?

18 A Yes.

19 Q And with respect -- when -- when the  
20 outcome that you're looking at is cancer, for -- for  
21 temporality a part of the question would be does the  
22 exposure come before the subject gets -- gets  
23 cancer, right?

24 A Yes.

25 Q And there's also, specifically with

1 respect to cancer, because it can be slower to  
2 develop, typically subjects are exposed to many  
3 factors, including environmental factors, that come  
4 before they develop cancer?

5 MR. NIGH: Object to form.

6 THE WITNESS: Well, I mean,  
7 temporality is just focusing on does the  
8 exposure come before the outcome, really. It's  
9 not talking about one exposure, different  
10 exposure. It's -- I mean, obviously, if -- if  
11 the exposure came after the outcome, then  
12 that's -- there's no causal link. So there has  
13 to be -- the exposure has to come before the  
14 outcome to -- to show a cause and effect  
15 relationship.

16 BY MR. GALLAGHER:

17 Q Okay. Going on to Page 35, the fifth  
18 factor is called biological gradient.

19 A Yes.

20 Q This is referring to essentially a  
21 dose response relationship; is that right?

22 A Yes.

23 Q That the greater the level of  
24 exposure -- if the -- if the risk of the outcome  
25 increases with increase in the level of exposure,

1 that can be one -- one factor that is indicative of  
2 a causal relationship, right?

3 A Yes.

4 Q Moving on to the bottom of that  
5 column, the sixth factor is plausibility.

6 A Yes.

7 Q For this factor, it's just a question  
8 of is the -- is there a suggestion that it's  
9 biologically plausible that the exposure is  
10 associated with the outcome -- or that the exposure  
11 is a causation of the outcome, right?

12 A Yes.

13 MR. NIGH: Form objection.

14 THE WITNESS: It asks -- it basically  
15 asks is there a plausible mechanism for this  
16 cause to -- for this exposure to cause the  
17 outcome.

18 BY MR. GALLAGHER:

19 Q Okay. And then the -- the -- moving  
20 on to the right-hand column of Page 35 the seventh  
21 factor is coherence. In your mind, how is coherence  
22 different from plausibility?

23 A So coherence to me is whether --  
24 whether there is a length between the plausibility,  
25 the basic science studies, and the --



1 THE COURT REPORTER: I'm sorry. The  
2 what and the clinical studies?

3 THE WITNESS: If -- if there is a --  
4 if there is a link or there is a nice flow, if  
5 you will, from the basic science animal studies  
6 and the clinical/epidemiological studies.

7 BY MR. GALLAGHER:

8 Q Okay. Moving on to the bottom of  
9 this, Page 35, in the right-hand column, the eighth  
10 factor is experiment. And essentially this is  
11 looking for experimental evidence, right?

12 A Yeah.

13 Q And that's experimental evidence  
14 that's different from -- it's not looking at an  
15 observational study but a true experiment or  
16 randomized control trial, right?

17 MR. NIGH: Form objection.

18 THE WITNESS: Yeah. I mean, again, I  
19 don't think it's clear enough on that, but most  
20 people take it to mean that it means a true  
21 experiment and, you know, in a randomized trial  
22 or an RCT.

23 Q And then on -- going on to Page 36,  
24 the ninth -- the ninth factor is analogy, right?

25 A Yes.

1 Q And this is just a question of are  
2 there -- I guess, what's your understanding of how  
3 this factor of analogy is applied?

4 A I'm just going to refer to my report  
5 just to refresh my memory.

6 Q Sure. It's on Page 27.

7 A Right. So analogy means that is there  
8 any evidence that carcinogens that are similar  
9 chemically, you know, similar in the chemical  
10 structure of the carcinogen in question also cause  
11 cancer. So sometimes people refer to it as a class  
12 effect, for example. So if one drug can cause an  
13 adverse event, then that -- sometimes, it's a class  
14 effect so that the group of drugs in that class of  
15 drugs can also cause that adverse event, which  
16 strengthens the analogy -- analogy argument.

17 But it generally means whether -- if  
18 we talk about the carcinogen, whether other  
19 carcinogens that are similar in structure also --  
20 have also shown to cause cancer.

21 Q Okay. Let's go up ahead and pull up  
22 your report, section -- report Page 29, and we can  
23 look at the table. And if you want to refer back to  
24 Pages 27 or 28, please -- you know, please feel free  
25 to.

1                   So I guess -- Sir Bradford Hill  
2       presented these -- one question -- Sir Bradford Hill  
3       presented these factors in a -- in a particular  
4       order. The first being strength, then consistency,  
5       then specificity, then temporality, then biological  
6       gradient, then plausibility, then coherence, then  
7       experiment and then analogy, right?

8           A           Right.

9           Q           And you haven't followed that -- that  
10       pattern. Is there any particular why -- particular  
11       reason why?

12                   MR. NIGH: Form objection.

13                   THE WITNESS: No, I don't think -- I  
14       don't think the pattern is important. I think  
15       it's the presence or the status of these  
16       variables that's important, not -- not -- I  
17       mean, it's not a temporal exercise. It's  
18       whether this variable exists, whether an  
19       analogy exists, whether temporality exists.

20       BY MR. GALLAGHER:

21           Q           Okay. With respect to -- with respect  
22       to the data that's in here, you've only included the  
23       Hidajat study, right?

24           A           Yes.

25           Q           You haven't included the studies or

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1 referred to the studies that suggest that there  
2 may -- that there was not a statistically  
3 significant observation of an association, right?

4 MR. NIGH: Form objection.

5 THE WITNESS: Again, we have talked  
6 about statistical significance. It's not a --  
7 it's not a -- statistical significance has not  
8 -- has nothing to do with the Bradford Hill  
9 criteria.

10 I have included the Hidajat because I  
11 felt that it satisfies this criteria more than  
12 the -- in this table. But I have included  
13 the -- the data from the dietary studies in my  
14 assessment from all the variables as well.

15 BY MR. GALLAGHER:

16 Q And the data -- the data that you're  
17 showing for strength of evidence, I guess -- where  
18 are you getting that data from? That's just --  
19 strike that.

20 The data that you're presenting for  
21 strength of evidence is just the odds ratios that  
22 were reported from the Hidajat study, right?

23 A It's the hazard ratios of the highest  
24 versus lowest NDMA categories.

25 Q From the Hidajat study, right?

1           A           Yes. Yes. It actually says in it on  
2           the -- on the bottom of the table.

3           Q           Sure. So are you looking at the first  
4           footnote, I guess, where there's the carat?

5           A           Yes.

6           Q           The numbers are --

7                       THE COURT REPORTER: I'm sorry. The  
8           numbers are what?

9                       MR. GALLAGHER: Numbers are from the  
10          study by Hidajat only.

11       BY MR. GALLAGHER:

12          Q           Is that correct?

13          A           Yes.

14          Q           And that carat is actually next to  
15          dose response. And dose response is presented --  
16          these data I think as you said, is the hazard ratio  
17          of the NDEA --

18          A           Yes. I mean, the dose response  
19          analysis is -- is the strength of the evidence,  
20          because they only, pretty much, did a dose response.  
21          So they -- they don't have a category of just other  
22          use -- you know, other risks of cancer with NDMA.  
23          They looked at a dose response, so that's -- that's  
24          why I could see the numbers duplicated because  
25          they're pretty much the same.

1           Q           So you essentially treated those --  
2     you treated those factors as the same, not  
3     different?

4           A           Right.

5                       MR. NIGH:   Form objection.

6     BY MR. GALLAGHER:

7           Q           In evaluating coherence, if we blow up  
8     on Page 29, Section IX, which is just above the  
9     table.

10          A           Yes.

11          Q           So you explain that from your  
12     perspective, coherence examines whether there's a  
13     link or coherence between basic science and  
14     epidemiological evidence, right?

15          A           Yes.

16          Q           And then in your -- but then in  
17     applying that, you say, "All nine cancers have been  
18     shown to have a causal link from well-designed large  
19     epidemiologic, occupational and scientific studies."

20                       It seems like you're assuming a causal  
21     link from the epidemiologic, occupational and  
22     scientific studies, right?

23                       MR. NIGH:   Form objection.

24                       THE WITNESS:  Well, that's -- I mean,  
25     that's -- that's where my -- I mean, I talk

1 about this in my opinion. Here, I use the word  
2 "causal" because they -- you know, if you look  
3 at the strength of the -- of the evidence and  
4 ratios and also the other -- the categories of  
5 Bradford Hill, they do satisfy the -- the  
6 different categories. And that's why I -- I  
7 use the word "causal."

8 Because when you get to coherence,  
9 then I have also looked at biologic  
10 plausibility, and analogy and all the other --  
11 this -- this is the last criteria. So I have  
12 already looked at all the other criterion and  
13 have, you know, determined my -- my opinion  
14 that I do believe there is causal link.

15 BY MR. GALLAGHER:

16 Q So you're not applying coherence. By  
17 the time you get here, you've decided there's a  
18 causal link, and it's based specifically on the  
19 strength of the association. That's what you said?

20 MR. NIGH: Form objection,  
21 mischaracterizes his testimony.

22 THE WITNESS: No. I disagree with  
23 that. By the time I got to coherence, I have  
24 looked at the other criteria as well.  
25

1 BY MR. GALLAGHER:

2 Q Right. But how -- how are you  
3 applying coherence here?

4 MR. NIGH: Form objection.

5 THE WITNESS: I am -- I am -- I'm  
6 stating that there -- because there is a link  
7 -- there is a causal link in terms of strength,  
8 temporality, biologic plausibility, that  
9 satisfies the coherence or the flow between the  
10 basic science data and the clinical data.

11 BY MR. GALLAGHER:

12 Q Okay. The data that you had looked  
13 at, though, were epidemiologic, occupational --  
14 well, let's break those down.

15 Epidemiologic and occupational  
16 studies, so those are like the Hidajat study, Straif  
17 study, right, the occupational studies? Those are a  
18 couple of occupational studies that you looked at?

19 MR. NIGH: Form objection, incomplete  
20 question.

21 You can answer.

22 THE WITNESS: And -- and the dietary  
23 studies, yes.

24 BY MR. GALLAGHER:

25 Q Okay. So the dietary studies would be



1 epidemiologic studies; is that right?

2 A Yes.

3 Q Okay. The dietary studies are not  
4 occupational studies, right?

5 A No.

6 Q What are the basic scientific studies  
7 that you're --

8 A Those are the animal studies that have  
9 shown NDMA can cause cancer.

10 Q If we go back to Page 28, looking at  
11 consistency, it's labeled VI.

12 A Uh-huh.

13 Q So, again, explain to me how you --  
14 how you've applied consistency here?

15 A Consistency means that there is basic  
16 science evidence suggesting of cancer, the  
17 causing -- the cancer-causing effects of NDMA in  
18 animals, and the occupational studies, mainly  
19 Hidajat. And many of the dietary epi studies have  
20 also shown that the -- the risk of cancer is  
21 increased. So that's the consistency.

22 Q So you say -- you say, mainly Hidajat.  
23 And in terms of consistency from Sir Bradford Hill,  
24 it seems like he was wanting -- be wanting to look  
25 at all of the studies, including studies that were

1 prospective and retrospective, right?

2 MR. NIGH: Form objection.

3 THE WITNESS: Hidajat was prospective,  
4 it was a prospective cohort where they followed  
5 men for 35 years. We have the dietary studies  
6 where they're a mixture, a mix of prospective  
7 and retrospective. And Bradford Hill does not  
8 say that -- he says there has to be evidence  
9 from, as you said, prospective and  
10 retrospective.

11 He doesn't say there has to be, you  
12 know, a consistent increase in risk in of all  
13 of the studies that you have. He's just  
14 suggesting that there has to be evidence from a  
15 mix of studies, which we do have here.

16 BY MR. GALLAGHER:

17 Q So wouldn't it be relevant to this  
18 factor of consistency, if there are studies that --  
19 some studies show -- in some studies, they reach  
20 statistical significance or an association, but that  
21 there's other studies where there's no statistically  
22 significant association? Isn't that inconsistent  
23 results?

24 A Again, a statistical significant has  
25 nothing to do with either the Bradford Hill criteria

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1 or consistency. And I think I've -- I've talked  
2 about the caveats of interpreting statistical  
3 significance. So if you'd just give me a few  
4 minutes, and I'll just read consistency from his  
5 paper again.

6 Q Sure.

7 A I mean mainly what it says is, "I  
8 would myself put a good deal of weight upon similar  
9 results" from prospective and retrospective studies.

10 Again, it doesn't say that all of  
11 these results have to be consistently showing an  
12 increased risk with that particular exposure. So  
13 he's -- he's quite -- he's quite general in his  
14 statement, and we do have in this question a mixture  
15 of prospective and retrospective epi -- epi and  
16 occupational studies.

17 Q So I'm not following. I think you  
18 said he's not requiring that the results are  
19 consistently showing the same --

20 A He's not --

21 MR. NIGH: Hold on. Let him finish  
22 his question.

23 BY MR. GALLAGHER:

24 Q I'll start over.

25 I heard you to say that your

1 interpretation of this, Doctor, is that  
2 Bradford Hill is not requiring that the studies  
3 consistently show the same observed association?

4 MR. NIGH: Objection, form and  
5 mischaracterizes his testimony.

6 THE WITNESS: Let me clarify. I'm  
7 just reading from what he's saying. "I would  
8 myself put a good deal of weight upon similar  
9 results reached in quite different ways, e.g.,  
10 prospective and" -- "prospectively and  
11 retrospectively."

12 And so -- so this -- I mean, this  
13 report and the findings does meet this  
14 criteria. I have retrospective studies and  
15 prospective studies. And it doesn't talk about  
16 the statistical significance or anything like  
17 that at all.

18 BY MR. GALLAGHER:

19 Q Well, but wouldn't it be relevant --  
20 wouldn't it be relevant to this, Doctor, if there  
21 are some studies that are concluding evidence of an  
22 association based on statistical significance, but  
23 there's other studies that are concluding no  
24 evidence of an association?

25 MR. NIGH: Form objection.

1 THE WITNESS: Again -- the  
2 Bradford Hill criteria is a method of looking  
3 at the totality of the evidence. You're rarely  
4 going to have a situation where all the studies  
5 that you have are consistently showing at one  
6 direction with minimal limitations. You're  
7 gonna have a mixed bag.

8 And I think that's why his -- I mean,  
9 the bar is quite low from what he's saying. He  
10 says, I want to see the, you know, results from  
11 a mix of prospective and retrospective. He's  
12 not going into any detail about, you know, what  
13 if some of them are negative, some of them are  
14 positive, what's the statistical significance.  
15 That's -- that's not -- at least that's not how  
16 I read it.

17 BY MR. GALLAGHER:

18 Q So from your perspective, this factor  
19 of consistency, it's not relevant if, among the  
20 studies that are being -- that have evaluated the  
21 question, some of them are positive and some of them  
22 are negative?

23 MR. NIGH: Object to form,  
24 mischaracterizes testimony.

25 THE WITNESS: I think I -- I think the

1 ones that have the highest weight and the  
2 stronger methodology, I think if those studies  
3 are showing an association -- plus there's, you  
4 know, evidence from animal studies. And as he  
5 says there's a mixed bag of prospective and  
6 retrospective. That to me, has satisfied his  
7 criteria.

8 Q So again, if there's -- if there's a  
9 mixed bag of some studies are positive and some  
10 studies are negative, wouldn't you consider that to  
11 be evidence of inconsistency?

12 MR. NIGH: Object to form.

13 THE WITNESS: In most situations,  
14 you're gonna have a mixed bag of studies, as I  
15 mentioned. If -- if you wanted to apply  
16 Bradford Hill to just questions that have only  
17 positive studies, you wouldn't -- you wouldn't  
18 be applying it a lot. So it all depends if the  
19 mixed bag, what -- you know, what -- what  
20 quality of evidence comes from those -- those  
21 mixed studies.

22 And here, I think that the study by  
23 Hidajat, has, you know, perhaps a high end  
24 rate. Plus the studies, the epi studies, and  
25 plus the data from animal studies, satisfy the

1 consistency criteria.

2 BY MR. GALLAGHER:

3 Q Okay. Let's go to -- let's go to the  
4 exhibit we were looking at early this morning, the  
5 article you had written about personal use of hair  
6 dyes and risk of cancer.

7 A Can you please -- can you please  
8 upload that again?

9 Q Sure.

10 MR. GALLAGHER: Can you put that back  
11 in the chat?

12 BY MR. GALLAGHER:

13 Q Do you have it?

14 A Yes.

15 Q Okay. We had looked at this this  
16 morning, and in this paper, you walk through the way  
17 you structured the searches for this, right?

18 A Yes.

19 Q And then you established -- you  
20 established inclusion criteria for collecting the  
21 data, right?

22 A Yes.

23 Q And then you set forth the way in  
24 which you did a quality assessment of the studies  
25 that were inclusive, right? And this is on

1 Page 2519. It's the fourth page of the article.

2 MR. NIGH: Form objection.

3 BY MR. GALLAGHER:

4 Q On the left-hand side.

5 Do you see that where you're  
6 describing the quality assessment that you had done?

7 A Yes.

8 Q And in that quality assessment, you  
9 came up with a series of criteria that were used to  
10 rank the quality of each of the studies; is that  
11 right?

12 A Yes.

13 Q And you would have come up with this  
14 quality assessment before deciding which -- which  
15 studies were of higher quality and which were of  
16 lower quality, right?

17 MR. NIGH: Form objection.

18 THE WITNESS: Usually, that's what  
19 quality assessments are done for, yes, used  
20 for.

21 BY MR. GALLAGHER:

22 Q Okay. Okay. You haven't described  
23 that type of quality assessment in your report for  
24 evaluating the -- the studies that you decided to  
25 include on which to base your opinions, have you?



1 MR. NIGH: Form objection.

2 THE WITNESS: I did not, because first  
3 of all, as you can see here, we have a lot of  
4 studies, that needs to be sifted through with  
5 different methodologies. In this case, I was  
6 mainly faced with two types of studies.  
7 Hidajat was one, and then the rest are all  
8 dietary studies with dietary questionnaires and  
9 very similar design.

10 So I preferred to kind of describe the  
11 methodology, the limitations and strengths  
12 rather than, you know, come up with a  
13 quality -- quality score.

14 BY MR. GALLAGHER:

15 Q So you haven't gone through this --  
16 sorry -- this -- of having criteria to evaluate  
17 these studies that you're relying on for quality,  
18 and then --

19 A No. And again -- another -- another  
20 reason is this --

21 MR. NIGH: Sorry. We couldn't hear  
22 the question because someone coughed. And that  
23 happens, I know. But can you please ask that  
24 question again?

25 MR. GALLAGHER: Sure. No worries.

1 BY MR. GALLAGHER:

2 Q So you haven't -- you haven't gone  
3 through the process of having criteria to evaluate  
4 the quality of the studies that you're including in  
5 your report on which your opinions are based,  
6 prospectively to describe the quality of each of  
7 them, right?

8 A Right. And I believe I did reply as  
9 to why. And if I could also add, qualities --  
10 although it was done here, and this was a quality  
11 score that we just came up ourselves, it's not a  
12 standardized quality score that's published. We  
13 just came up with it ourselves.

14 But there's really no evidence that a  
15 quality score would necessarily improve the quality  
16 of the review when -- you know, when the strengths  
17 and limitations of the studies in the review are  
18 discussed and sort of analyzed. And with the fact  
19 that, again, the studies are very similar in design,  
20 I choose not to use the quality score.

21 Q Okay. When you say "they are similar  
22 in design," I thought we had discussed earlier this  
23 morning, that all of the studies have different  
24 designs, right?

25 A Well --

1 MR. NIGH: Form objection. Form  
2 objection.

3 Go ahead. You can answer.

4 THE WITNESS: So, you have -- you have  
5 pretty much one occupational study that I  
6 relied on, and that's in Hidajat. And I talked  
7 about that extensively in more than a couple of  
8 pages. And then -- so that's obviously  
9 different than the epi studies.

10 But then the epi studies are pretty  
11 much very similar in design. That's what I  
12 meant. So you have two types of designs,  
13 occupational and epi. And then the epi are  
14 very similar in design. They are all  
15 questionnaire-based dietary studies.

16 So if I had a number of randomized  
17 trials, a number of occupational studies, a  
18 number of dietary epi studies and number of  
19 studies on different designs, then that may  
20 have warranted a quality score.

21 But because of the small number of  
22 studies and -- and the -- and the fact that I  
23 felt I could describe them, the strengths and  
24 limitations and the fact that really, quality  
25 scores, although intuitively, they look -- they

1 sound good for observational reviews, have not  
2 really shown to improve the -- you know, to  
3 change the quality of the review if that review  
4 does contain a formal discussion of the  
5 limitations and strengths of the studies  
6 included.

7 BY MR. GALLAGHER:

8 Q Okay. Can we look at the Straif paper  
9 again?

10 A Sorry, which paper?

11 Q Exhibit 7, Straif.

12 This was another occupational study  
13 looking at the workers in the rubber industry,  
14 right?

15 A Yes.

16 Q On Page 19 of your report, you're  
17 looking -- you're discussing your opinion with  
18 respect to pancreatic cancer?

19 A Yes.

20 Q And you -- you criticize the Straif  
21 study as being, in your opinion, underpowered to  
22 examine pancreatic cancer deaths, right?

23 A Yes.

24 Q And that's because there were only 15  
25 pancreatic cancer deaths in the cohort for the

1 Straif study, right?

2 MR. NIGH: Form objection.

3 THE WITNESS: Right.

4 BY MR. GALLAGHER:

5 Q So isn't it -- isn't it the case that  
6 at least for the cohort that Straif was looking at,  
7 there weren't very many members of that cohort that  
8 had pancreatic cancer or died from pancreatic  
9 cancer, right?

10 MR. NIGH: Object to form.

11 THE WITNESS: So 15 cases only.

12 BY MR. GALLAGHER:

13 Q Right. So the -- the powering of the  
14 study is -- is based largely off of sample size, and  
15 the expected size of a potential association, right?

16 MR. NIGH: Form. Form objection.

17 THE WITNESS: So there are about four  
18 criteria for the power. One of them is sample  
19 size or, more specifically, number of events.

20 BY MR. GALLAGHER:

21 Q Okay. If you look -- let's look at  
22 the Straif study, on Page 181, in the right-hand  
23 column just above the table.

24 A Okay.

25 Q Do you see where they're describing

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1 for this cohort, they "assessed exposure to total  
2 nitrosamine because animal studies indicated linear  
3 additive carcinogenicity for exposure to low  
4 concentrations of different nitrosamines and because  
5 assessment of exposure to specific nitrosamines  
6 would not have been possible." Right?

7 A Okay.

8 Q So for this -- for this study,  
9 assessment of the exposure to specific nitrosamines  
10 would not have been possible, right?

11 A Right.

12 Q If we go to Page 185 in the left-hand  
13 column, the -- the top, the first full sentence,  
14 they state, "We have discussed previously that the  
15 increased risk of stomach cancer among rubber  
16 workers was mostly found in work areas with  
17 relatively low exposure to nitrosamine."

18 Do you see that?

19 A What page is that? I'm trying to look  
20 at in my PDF. What page is that?

21 Q Sure. It's Page 185. 185, the top  
22 left-hand column. Do you see that sentence where  
23 they --

24 A Yes.

25 Q -- say, "We have discussed previously

1 that the increased risk of stomach cancer among  
2 rubber workers was mostly found in work areas with  
3 relatively low exposure to nitrosamine"?

4 A Right. And they reference two  
5 studies. Okay.

6 Q So wouldn't that be inconsistent with  
7 a suggestion that among rubber workers, it was  
8 nitrosamine that was leading to an increased risk of  
9 stomach cancer?

10 MR. NIGH: Form objection.

11 THE WITNESS: First of all,  
12 nitrosamines are a more general, as you know,  
13 chemical name that includes NDMA.

14 And I mean, here, I'm just reading one  
15 sentence from the paper. I have to go and read  
16 the paper and see whether I believe those  
17 results or not. So I mean, that's what they're  
18 saying. I can't just go with what they're  
19 saying. I haven't reviewed those two articles.

20 BY MR. GALLAGHER:

21 Q Okay. But -- but at least these  
22 authors who are reporting in this study that you  
23 have chosen to include -- include in your report are  
24 describing that from their perspective, they have  
25 previously shown that any increased risk of stomach

1 cancer among rubber workers was mostly found in work  
2 areas with relatively low exposure to nitrosamines,  
3 right?

4 MR. NIGH: Form objection.

5 THE WITNESS: Again, even -- even in  
6 this study, they only have 44 cases of stomach  
7 cancer deaths, which leads to -- you know, as  
8 expected, a very wide confidence interval.

9 So if -- if that study that they're  
10 mentioning is similar to this study, it may be  
11 because, again, it -- it was a very low -- in a  
12 small number of stomach cancer cases. And  
13 unlike Hidajat, it did not control for death by  
14 other causes.

15 So, yes, that's what they're saying,  
16 but I don't -- I'm not sure if I, you know,  
17 believe their -- their methodology.

18 BY MR. GALLAGHER:

19 Q Okay. Back to your report, Page 19  
20 over to Page 20?

21 A I'm sorry. Can I just mention -- can  
22 we -- after you ask your question on Page 19, can we  
23 take a ten-minute break?

24 Q Sure. Absolutely.

25 Let me just ask this quick question,



1 and then -- and then we'll take a break.

2 So you discount the Straif study and  
3 are relying on the Hidajat study with respect to  
4 your opinions for pancreatic cancer, right?

5 MR. NIGH: Form objection.

6 THE WITNESS: For pancreatic cancer, I  
7 also do mention the Zheng study and I mention  
8 the Fritz -- Fritschi study.

9 Q What's the -- what's the second study  
10 you just referred to, Fritschi?

11 A Yeah.

12 Q Well, the -- the Fritschi study,  
13 F-r-i-t-s-c-h-i, you'll agree with me did not find  
14 an association --

15 A That's correct.

16 Q -- between nitrosamines and pancreatic  
17 cancer, right?

18 A That's right.

19 Q And you discounted the Straif study,  
20 which also did not show an association of NDMA -- or  
21 of nitrosamines and pancreatic cancer, right?

22 MR. NIGH: Form objection.

23 BY MR. GALLAGHER:

24 Q And you do rely on the Hidajat study  
25 in support of your opinion regarding the association

1 of NDMA and pancreatic cancer, right?

2 A And -- and Zheng.

3 Q Sure. Okay. I'll get to Zheng in a  
4 minute.

5 A Okay.

6 Q So -- but the Hidajat study as we  
7 discussed earlier today, was one of occupational  
8 exposure where the exposure is primarily inhalation  
9 or contact through skin, right?

10 A Yes.

11 Q Okay.

12 MR. GALLAGHER: Why don't we take a  
13 ten-minute break now, and we'll pick up with  
14 the Zheng study when we come back.

15 THE WITNESS: Sure.

16 THE VIDEOGRAPHER: The time is now  
17 2:30. This ends Media Unit Number 4. We're  
18 going off the record.

19 (Whereupon, a short break was taken.)

20 THE VIDEOGRAPHER: The time is now  
21 2:49. This begins Media Unit Number 5. We're  
22 back on the record.

23 BY MR. GALLAGHER:

24 Q Dr. Etminan, I'm going to mark as  
25 Exhibit 20 an article by Zheng, Z-h-e-n-g entitled

1 "Dietary N-nitroso Compounds and Risk of Pancreatic  
2 Cancer: Results From a Large Case Control Study."

3 (Whereupon, Exhibit 20 was marked for  
4 Identification.)

5 THE WITNESS: Which exhibit is this?

6 Sorry, 37?

7 Q Exhibit 20.

8 A Oh, 20. Okay.

9 Q It's Exhibit 20. It is -- you have  
10 cited it on Page 20 of your report, and it's  
11 Reference 37 from -- from your report.

12 If we go to Page 258, Table 2?

13 A I'm sorry. Can you just give me  
14 30 seconds to find this in my report?

15 Q Sure. It's on Page 20 of your report.

16 A Oh, 20, okay.

17 Q And if you want we can -- sorry to --  
18 we can --

19 A On Page 20 is -- on Page 20, I talk  
20 about Zheng and Straif, Loh. I don't see Jane.

21 Q Z-h-e-n-g.

22 A Oh, Zheng.

23 Q Sorry. My apologies if I'm  
24 mispronouncing it.

25 A That's all right.

1 So it's number, which one, sorry.

2 Q It's Exhibit 20.

3 A Is it uploaded?

4 Q I believe it is now.

5 A All right.

6 Q Do you see it?

7 A Yes, I see it.

8 Q Okay. If we go to Page 258, Table 2.

9 A Yeah.

10 Q And Table 2 is presenting "Adjusted  
11 odds ratios and 95 percent confidence intervals for  
12 pancreatic cancer risk according to quartiles of  
13 consumption of certain N-nitroso compounds," right?

14 A That's right.

15 Q And if we -- if you look down to NDMA,  
16 the adjusted odds ratio for NDMA exposure as -- in  
17 association with pancreatic cancer is 0.13, right?

18 A Yes.

19 Q That's essentially evidence of no  
20 association between exposure to NDMA and risk of  
21 pancreatic cancer in this study, right?

22 A For the general NDMA, yes.

23 Q Okay. For the general NDMA. And then  
24 if we look at -- it also separately presents an odds  
25 ratio for NDMA from plant source, right?

1 A Yes.

2 Q And the adjusted odds ratio for NDMA  
3 from plant sources is 1.93; is that right?

4 A Yeah.

5 Q And then separately, it breaks out  
6 NDMA from animal sources and the adjusted odds ratio  
7 for risk of pancreatic cancer and exposure to NDMA  
8 having an association of 1.7, right?

9 A Right.

10 Q So for exposure to NDMA from animal  
11 sources that's, again, evidence of no association  
12 between exposure to NDMA from animal sources and  
13 risk of pancreatic cancer, right?

14 A Yeah.

15 Q So don't you think these results  
16 are -- at a minimum, the results for plant NDMA from  
17 plant sources are inconsistent with the results for  
18 NDMA and results for NDMA from animal sources,  
19 right?

20 MR. NIGH: Form objection.

21 THE WITNESS: It is inconsistent, but  
22 I think that's something that should be -- I  
23 mean, you can't disregard it. I mean, they  
24 are -- they are not consistent. But if you  
25 can't -- you can't disregard the fact that

1           there is a signal with plant sources, but of  
2           course, not with NDMA from animal sources.

3       BY MR. GALLAGHER:

4           Q           Okay. And -- and we also can't  
5       disregard that the data for NDMA is showing no  
6       association of exposure to NDMA and risk of  
7       pancreatic cancer, right?

8                       MR. NIGH: Form objection.

9                       THE WITNESS: Well, it -- it -- it  
10       shows -- it doesn't show a risk for general  
11       NDMA, right.

12       BY MR. GALLAGHER:

13           Q           Okay. You'd agree with me that the  
14       exposure to NDMA from valsartan is not exposure to  
15       NDMA from plant sources, right?

16                       MR. NIGH: Object to form.

17                       THE WITNESS: And it's not from  
18       animals either. But I mean, the molecule --  
19       the molecule is the molecule. So I don't know  
20       if -- whether it comes from the plant -- I  
21       mean, it comes from the plant. But in the  
22       body, it gets broken down to the chemical NDMA.  
23       So whether it comes from a plant or any other  
24       source, I don't think that really matters that  
25       much.

1                   It's just like, you know, getting  
2           protein from dairy or from meat. Once it's  
3           broken down to its amino acids, it's -- it's  
4           protein in the body. It does what it's  
5           supposed to do.

6       BY MR. GALLAGHER:

7           Q           Okay. Do you have any explanation for  
8       why they might observe from plant sources NDMA, a  
9       hazard ratio of 1.93, but for NDMA generally and  
10      NDMA from animal sources, there's no evidence of  
11      association?

12          A           I -- I don't. But again, I think that  
13      it -- I mean, it is a piece of evidence that should  
14      be looked at in -- in -- in the grand scheme of all  
15      the evidence. And that's why I did talk about it in  
16      my report. I mentioned that no association with  
17      animal studies -- with the animal sources, but also  
18      did mention with the plant sources.

19                    So I think it's one piece of the  
20      puzzle that should be -- should be looked at. If --  
21      if the plant source was also a negative, then I  
22      would say we can disregard it. But since the plant  
23      source does show a signal and maybe we can't really  
24      explain why. But we can't really disregard the  
25      signal.

1           Q           So you said if the plant sources were  
2           negative, then we could disregard it. Are you  
3           disregarding studies that show no association?

4                   MR. NIGH: Object to form,  
5           mischaracterizes testimony.

6                   THE WITNESS: No, but what I meant to  
7           say is that if the plant source was also -- was  
8           showing a negative association, we could say  
9           that NDMA in the study does not show a link.  
10          But -- but it -- but it does show a link from  
11          plants and not animals. So we can't totally  
12          disregard it because of that reason.

13       BY MR. GALLAGHER:

14          Q           Okay. Is it possible that there's  
15          some unmeasured confounding factor for those who are  
16          getting NDMA from plant sources that explains the  
17          inconsistency in this data?

18          A           I mean, I can't think of a measured  
19          confounder that only affects plant users, but I  
20          mean, I don't know. I -- I wouldn't speculate.

21          Q           Is it possible that there's some  
22          factor for which there's an interaction with NDMA  
23          that those who are -- have a diet higher in plant  
24          sources than NDMA have -- that hasn't been measured  
25          here, and that's creating the inconsistency in the



1 results?

2 A I mean, I -- that's the next -- I  
3 don't -- again, I don't want to speculate. It's not  
4 really within my expertise to -- to opine on.

5 Q Okay. So getting back to your report  
6 with respect to pancreatic cancer, as we talked  
7 about on Pages 19 and 20, you cite to the Fritschi  
8 article?

9 A Yes.

10 Q Which reported no association of  
11 nitrosamines and pancreatic cancer.

12 You cite to the Straif article, which  
13 again found no evidence of an association between  
14 nitrosamines --

15 A Again, just to clarify, Straif was  
16 inconclusive because of a very small number of  
17 cases. And Fritschi, I do explain the limitations  
18 in my report.

19 Q Right. Okay. But neither of those --  
20 neither of those are supportive -- are evidence for  
21 an association of NDMA with pancreatic cancer,  
22 right?

23 A Correct.

24 Q And then you cite the Hidajat study,  
25 which we have discussed previously, right?

1 A Yes.

2 Q And then the Zheng study, which we've  
3 just looked at, for NDMA generally, is showing no  
4 evidence of an association of NDMA and pancreatic  
5 cancer, right?

6 A For general NDMA, yes.

7 Q Okay. So you've cited four articles.  
8 Three of them have no evidence for an association.  
9 One of them where the mechanism -- method of  
10 exposure was through inhalation or skin contact more  
11 than oral.

12 And it's essentially on the basis of  
13 that -- that one study that you're concluding the  
14 dietary and occupational evidence demonstrates an  
15 increase in the risk of NDMA and NDEA with  
16 pancreatic cancer, right?

17 A Yes. So I say the -- so I say the  
18 constellation of animal studies, the -- the large  
19 occupational studies that probably has a higher rate  
20 in terms of methodology and one increased risk of  
21 NDMA plant-based on one study. I'm kind of looking  
22 at the totality of the evidence for that.

23 THE COURT REPORTER: Counsel, I'm  
24 sorry. I need to just -- I need to take one  
25 minute.

1 MR. GALLAGHER: Okay. Can we go off  
2 the record?

3 THE VIDEOGRAPHER: The time is now  
4 3:02. We're going off the record.

5 (Whereupon, a short break was taken.)

6 THE VIDEOGRAPHER: The time is now  
7 3:03. We're back on the record.

8 Mr. Gallagher, I think you're on mute.

9 MR. GALLAGHER: Sorry. Thank you.

10 BY MR. GALLAGHER:

11 Q Dr. Etminan, I want to explore this  
12 concept of totality of evidence with you.

13 A Okay.

14 Q So with -- with respect to pancreatic  
15 cancer, you have cited to three studies that show no  
16 evidence of an association of NDMA with pancreatic  
17 cancer. And you cite to one article again where the  
18 method of exposure was primarily inhalation or skin  
19 contact, not oral.

20 And based on that one study, you're  
21 telling us that the totality of evidence is  
22 supportive of an association of exposure to NDMA and  
23 the risk for pancreatic cancer; is that right?

24 A So --

25 MR. NIGH: Object to form.

1                   Hold on. Let me make my objection,  
2                   please.

3                   Object to form, and mischaracterizes  
4                   testimony.

5                   THE WITNESS: So totality doesn't mean  
6                   just looking at what -- how many positive  
7                   studies you have and how many negative studies  
8                   you have. First of all, I -- I included three  
9                   negative studies because they included my --  
10                  they met my search criteria in my report. And  
11                  so I had to talk about them, and I -- they were  
12                  negative, and I had to talk about the  
13                  limitations.

14                  And one of those three studies is  
15                  Straif that -- that you mentioned, could not --  
16                  with 15 cases, could not really study the  
17                  question. So it wasn't really a negative  
18                  study. It wasn't a well-designed study that  
19                  led to a negative results. It was a very small  
20                  study that could not answer the question.

21                  Fritschi also combined different  
22                  exposures. I talked about the limitations of  
23                  that study. And the -- when I say totality,  
24                  yes, I believe that the study by Hidajat  
25                  carries more of the weight because it was very

1 long follow-up, good sample size. Yes, it  
2 wasn't oral NDMA. I don't think we could ever  
3 have an oral -- orally-based NDMA exposure  
4 study that's well designed and can follow  
5 patients for a long time. I think logistically  
6 and ethically, that's impossible.

7 But the -- over time, the data that we  
8 have from animal studies and other data over  
9 time, exposure to skin and lungs can lead to  
10 systemic absorption of NDMA.

11 So to answer your question, it is not  
12 just three negative, one positive, I decided on  
13 the positive. It's -- it's the quality of the  
14 event. It's the weight of the evidence that  
15 goes into that decision.

16 BY MR. GALLAGHER:

17 Q Well, wouldn't the dietary studies be  
18 looking at oral -- oral exposure to NDMA to the  
19 extent they're being based on assumptions of the  
20 estimates for the amount of NDMA in particular  
21 foods?

22 A Yes, they do. But, again, they also  
23 have limitations that, for example, Hidajat did not.  
24 And then most of their limitation would be -- that's  
25 why potentially it's that some of them are negative

1 is the -- the follow-up was not as long as Hidajat  
2 to -- for -- to allow cancers to form.

3 And they did not control for competing  
4 deaths or deaths of other causes. So if somebody  
5 died of a heart attack, they were out of the study.  
6 They could not get cancer. That would lead to a  
7 smaller number of cancer cases.

8 So, yes, the dietary studies may --  
9 may mimic -- may better mimic the valsartan  
10 scenario, but they -- they have other limitations  
11 that -- that may prevent them from showing a -- you  
12 know, an effect -- an increase in risk with NDMA and  
13 cancer.

14 Q Okay. Understanding that the dietary  
15 studies do have limitations, and I think we had  
16 discussed some of those earlier today, one of the --  
17 one of the limitations of Hidajat study is that the  
18 method of exposure -- strike that.

19 With respect to assessing exposure to  
20 NDMA from valsartan, which would be oral, one of the  
21 limitations of the Hidajat studies as a -- as a  
22 basis for evaluating that question, is that the  
23 method of exposure is primarily inhalation or direct  
24 contact with skin, not oral exposure, right?

25 A Yes, I think we talked about it.

1 Q Okay. Moving on in your report to  
2 head and neck cancers?

3 A Okay.

4 Q So the first -- the first study cited  
5 here is Loh, L-o-h.

6 A All right.

7 Q And for this, the observed relative  
8 risk is 1.13; is that correct?

9 A Yes.

10 Q And this is exhibit -- the article is  
11 Exhibit 15, if you want to look at it. But at the  
12 moment, we can just look at Page 20 of your report.

13 A Okay.

14 Q So you agree that that was not  
15 statistically significant evidence for an  
16 association of NDMA and esophageal cancer, right?

17 A Yes.

18 Q Okay. And the confidence interval is  
19 from 0.77 to 1.68, right?

20 A Yes. And, again, we have talked about  
21 imprecision and the very low and very high limits  
22 and what that means. But, yes --

23 THE COURT REPORTER: But, yes, what?

24 THE WITNESS: It wasn't statistically  
25 significant.

1 BY MR. GALLAGHER:

2 Q In your report, you focus on the upper  
3 bound of that confidence interval. I want to talk  
4 for a minute about the lower bound of the confidence  
5 interval, 0.77.

6 So the -- according to this data, it  
7 would be the -- the likelihood of the actual  
8 relative risk being 0.77 is as good as the  
9 possibility that the actual relative risk is 1.68.  
10 Do I understand that right?

11 A I -- I don't -- I don't think I agree  
12 with that. But I do agree that it's -- and you can  
13 say it's an inconclusive result. I don't know if  
14 the probability of getting .77 is the same. I mean,  
15 it could be similar. It could be a bit -- I  
16 can't -- that's a technical statistical question. I  
17 can't -- I have to, kind of, maybe, go back and look  
18 at it.

19 But for the purposes of our  
20 discussion, I'm comfortable in saying that it's --  
21 because it goes from very low to very high, that  
22 it's inconclusive. But, again, if it went from very  
23 low to, let's say, 1.2, 1.3, I would be more  
24 comfortable saying it's negative. But because it's  
25 going all the way up to 1.68, I'm more comfortable



1 in saying it's inconclusive.

2 MR. NIGH: And I would object to the  
3 form of that last question.

4 BY MR. GALLAGHER:

5 Q If we look at Exhibit 15, the Loh  
6 study, turning to Page 1057, I believe, just below  
7 Table 2 --

8 A Yes.

9 Q -- on the left-hand side?

10 A Table 2, okay.

11 Q Yeah. Sorry, just below -- just below  
12 Table 2.

13 A Okay.

14 Q And this is -- these studies are  
15 evaluating multiple cancers. So this is carrying  
16 over from the prior page where they say, "There was  
17 no significant association with esophageal and  
18 stomach cancers for all three exposures."

19 Do you see that?

20 A Which -- which -- are you looking at a  
21 table or --

22 Q No. I'm sorry. I'm looking just  
23 below the table.

24 A Below Table 2?

25 Q Yes. And it's -- it's going from

1 the -- the sentence starts at the end of Page 1056,  
2 the prior page and carries over to Page 1057.

3 A Yeah. I mean, I -- I think that's  
4 also reflected in Table 5. But in Table 5, they  
5 also -- they also show the number of cases, and as I  
6 mentioned before, with 55 cases of esophageal  
7 cancer, that does not give you a very precise  
8 estimate. So, yeah, it's not statistically  
9 significant because it's probably not supposed to be  
10 this small number of cases.

11 Q And the small number of cases is due  
12 in part because relatively few people in this cohort  
13 actually got -- actually had esophageal cancer,  
14 right?

15 A Well, again, from the table, it seems,  
16 like, compared to the other types of cancer, they --  
17 this group had a smaller -- you know, had a smaller  
18 number of cases. I'm not sure what the percentage  
19 would be. I don't think they -- they have that as  
20 to the percentage of patients in this study who had  
21 esophageal cancer. But we just have the number of  
22 esophageal cancers from the total number of cancers,  
23 and it seems to be low.

24 Q Let's look at -- have we already  
25 marked the Kefzei article? Exhibit 16, the Kefzei,

1 article. And you're citing to this on Page 21 of  
2 your report, with respect to --

3 A Please hold on.

4 Q Okay.

5 A Okay.

6 Q Again, now the -- the observed hazard  
7 ratio is 1.15, right?

8 A For which cancer? Are you looking at  
9 a specific table?

10 Q Oh, I'm sorry. The -- I'm looking at  
11 your report. And you're more than welcome to look  
12 at it.

13 A 1.15, yes.

14 Q For esophageal cancer?

15 A Uh-huh.

16 Q You had earlier -- when you were  
17 discussing Keszei with respect to gastric cancer?

18 A Yes.

19 Q You had criticized this article  
20 because of potential misclassification and  
21 inaccurate reporting the different food intake by  
22 the subjects. Do you remember that?

23 MR. NIGH: Form objection.

24 THE WITNESS: Yes.

25

1 BY MR. GALLAGHER:

2 Q Okay. That potential for  
3 misclassification applies as equally for esophageal  
4 cancer as it does for gastric cancer, right?

5 MR. NIGH: Form objection.

6 THE WITNESS: It does, but, usually  
7 misclassification that affects both groups,  
8 usually, gives no results, which we got for  
9 stomach cancer. Here, we have, you know, a  
10 statistically significant increase in risk.

11 So, again, there has to be a very  
12 clear mechanism as to how misclassification is  
13 causing this increase in risk where --  
14 esophageal because usually misclassification  
15 that's non-differential just dilutes the  
16 effect, which we --

17 THE COURT REPORTER: Between what?

18 THE WITNESS: Dilutes the effect. But  
19 here, we do see a slight increase in risk  
20 with -- in Kefzei with esophageal cancer.

21 BY MR. GALLAGHER:

22 Q Well, but you don't know if -- if  
23 there's inaccurate reporting, either inaccurate  
24 recording by the study subjects of what their actual  
25 dietary intake is, or inaccurate assumptions about

1 the estimates of what the actual content of NDMA is  
2 in each of the specific foods?

3 MR. NIGH: Form objection.

4 BY MR. GALLAGHER:

5 Q The data is going to be inaccurate.  
6 You don't know what -- what the effect is going to  
7 be.

8 MR. NIGH: Is that the end of the  
9 question?

10 MR. GALLAGHER: Yes.

11 MR. NIGH: Form objection.

12 THE WITNESS: Yeah. We -- we don't  
13 know. And, again, I'm just saying,  
14 misclassification of a questionnaire would  
15 usually lead to null -- or null results. And  
16 we don't know what could have happened here.  
17 They're different subjects.

18 The other -- the other potential  
19 possibility is that, again, more of the -- I'm  
20 just making this -- I'm making this inference  
21 based on epi study design and the data. It's  
22 possible that more of the cancer patients  
23 with -- stomach cancer patients -- I'm sorry.  
24 More of the patients who were followed died  
25 before they got stomach cancer versus the --

1           those who got esophageal cancer probably could  
2           have survived longer to get esophageal cancer.  
3           So these are just sort of inferential  
4           possibilities based on the data and their study  
5           design that they present.

6       BY MR. GALLAGHER:

7           Q           You have no basis, though, for  
8           suggesting -- for saying that the -- the people who  
9           ultimately got esophageal cancer just survived  
10          longer than the people who got gastric cancer?

11                       MR. NIGH:   Form objection.

12                       THE WITNESS:   Again, we don't have --  
13          we are not privy to any of this data.   But from  
14          the -- from the fact that they followed these  
15          patients and looked at three related cancers,  
16          they don't talk about how many died and dropped  
17          out and any control for competing, you know,  
18          events, such as death, and making an  
19          inferential sort of suggestion that these could  
20          be possibilities.   Yes, of course, I don't  
21          know.   I don't think anybody would know unless  
22          you actually had access to the data and  
23          could -- you know, could analyze the data and  
24          ask more questions.

25

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1 BY MR. GALLAGHER:

2 Q Okay. And then in your -- in your  
3 report, again on Page 21, you go on and discuss the  
4 Straif study and the Hidajat study, right?

5 A Yes.

6 Q Neither of those studies controlled  
7 for alcohol use, correct?

8 A No. But, again, my analysis for one  
9 unmeasured confounder, which could be alcohol,  
10 showed -- with using the E-value that we talked  
11 about earlier, showed that the effect of that one  
12 unmeasured confounder, that could be alcohol, has to  
13 be very large to make the results, you know, not --  
14 you know, take the results to 1, basically.

15 So they did not -- they did not  
16 control for alcohol in their study. But, again, I'm  
17 using a simulation. I have shown that one  
18 unmeasured confounder would not have changed the  
19 results.

20 Q Okay. Well, alcohol is a strong risk  
21 factor for cancer of the pharynx, larynx and  
22 esophagus, right?

23 A Right. And, again, remember, based on  
24 our discussion, the risk factor is not as  
25 detrimental as a confounder. In this case, it

1 actually is a confounder for -- for esophageal and  
2 stomach cancers. And that's why it could fit that  
3 unmeasured confounder scenario that I show, you  
4 know, what happens if you have that unmeasured  
5 confounder and how much -- how strong that  
6 confounder has to be to make the results known.

7 So in a way, I did simulate for it --  
8 but it was -- it was not controlled for in the  
9 study.

10 Q Okay. And the same for -- for  
11 smoking. The Straif study didn't control for  
12 smoking, right?

13 A The -- the Hidajat study simulated --

14 Q That wasn't my question.

15 My question was the Straif study  
16 didn't control for smoking, right?

17 A The Straif study --

18 MR. NIGH: Hold on. If you can please  
19 not interrupt the witness. I don't know if he  
20 finished that last question -- answer, but  
21 please don't interrupt him going forward.

22 You can answer, Doctor.

23 THE WITNESS: No. I think I have  
24 finished my question. Let me just pull Straif  
25 again because you --



1 BY MR. GALLAGHER:

2 Q Sure. Yup.

3 A So the Straif did not adjust for  
4 smoking. But again, the main problem with Straif  
5 was with 15 cases, even if they had smoking, it  
6 wouldn't have done anything because you have so --  
7 small number of cases that, I mean, controlling for  
8 smoking would be a moot point within the data, to  
9 move the needle, if you will.

10 Q Okay. And the Hidajat study, as we  
11 discussed, did not directly control for smoking,  
12 correct?

13 A They did not directly control, but  
14 they simulated smoking data in their study.

15 Q Okay. So now we have just talked  
16 about two factors that haven't been accounted for in  
17 these studies. In your --

18 A I -- I -- I sort of disagree with  
19 that.

20 I -- when you simulate smoking data  
21 and see if that changes the results or not, that  
22 is -- I mean, that is not -- it may not be the same  
23 as having the variable, but it -- it does -- I mean,  
24 you have to give it some weight. If it doesn't  
25 change your results, you can't just say, you know,

1 they didn't control for it.

2 Q Okay. Well, they haven't adjusted  
3 for --

4 A They didn't have the --

5 Q None of these studies adjusted for --

6 A Right.

7 THE COURT REPORTER: I'm sorry.

8 Adjusted for what?

9 MR. GALLAGHER: Alcohol use or tobacco  
10 use.

11 BY MR. GALLAGHER:

12 Q And just a minute ago, you were  
13 referring to this E-value methodology?

14 A Yes.

15 Q Magnitude of an unmeasured variable to  
16 reverse the risk, right?

17 A Yes.

18 Q What if there's two unmeasured  
19 variables?

20 A This methodology only works with one.  
21 It only works for one unmeasured confounder.

22 Q Okay. So it does -- it doesn't work  
23 if there's multiple unmeasured confounders?

24 A It does not, but, again, when you talk  
25 about confounders, as I talked about earlier -- I

1 mean, alcohol use in gastric cancer and -- and in  
2 this question is a true confounder.

3 But there may be other variables that  
4 may look like a confounder. They may not be actual  
5 confounders. And the fact that they're not  
6 controlled for does not necessarily mean that had  
7 they been present, they would have changed the  
8 results, again, because you could have a classic  
9 confounder. But if the prevalence of that  
10 confounder is very low or its association with the  
11 outcome and the exposure is very low, it may not  
12 affect the results at all.

13 So I think it's a bit premature to say  
14 I don't want to believe these results because they  
15 didn't control for these unmeasured confounders.  
16 It's something to think about and sort of factor in,  
17 but I think there are caveats to it.

18 Q Okay. And then moving on in your  
19 report, you also address the Knekt study?

20 A Yes.

21 Q Do you see that towards the bottom on  
22 Page 21?

23 And you would agree with me that Knekt  
24 did -- did not find statistically significant  
25 evidence of an association between exposure to NDMA

1 and risk of head and neck cancers, right?

2 A It found an increased risk, a  
3 1.37 relative risk that was not statistically  
4 significant.

5 Q Okay. Okay. Talking for a minute  
6 about when you're doing -- looking at data from an  
7 observational study, in theory, if there's no  
8 association between the exposure and the outcome,  
9 the relative risk is 1.0, right?

10 MR. NIGH: Form objection.

11 THE WITNESS: Yes, that's possible.

12 BY MR. GALLAGHER:

13 Q Well, is it possible, or is that --

14 A I mean, no. That -- that scenario --  
15 that scenario is possible that you could have -- you  
16 could have no association in a study with a relative  
17 risk of 1.0.

18 Q Okay. I'm -- if -- if -- by  
19 definition, if there's no association between an  
20 exposure and an outcome, the relative risk is 1.0?

21 MR. NIGH: Object to form.

22 THE WITNESS: Yes.

23 BY MR. GALLAGHER:

24 Q Okay. And if the relative -- if, in  
25 fact, the exposure is protective against having the

1 outcome, the relative -- the actual relative risk is  
2 below 1, correct?

3 A Yeah, yes.

4 MR. NIGH: Form objection.

5 BY MR. GALLAGHER:

6 Q And if the -- if there's a positive  
7 association between the exposure and the outcome,  
8 the relative risk, the actual relative risk, is  
9 above 1, right?

10 MR. NIGH: Form objection.

11 THE WITNESS: Yes.

12 BY MR. GALLAGHER:

13 Q In practice, when you're looking at  
14 data from an observational study, you would rarely  
15 observe data where the observed relative risk is  
16 exactly 1.0, correct?

17 MR. NIGH: Object to form.

18 THE WITNESS: I mean, because I read a  
19 lot of papers, I have -- I wouldn't say it's  
20 that rare. I mean, it happens.

21 BY MR. GALLAGHER:

22 Q Sure. It can happen, but observation  
23 of a relative risk of data where the measured  
24 relative risk is above 1 does not mean there is an  
25 association, right?

1 MR. NIGH: Object to form.

2 THE WITNESS: Again, you are -- you're  
3 only looking at a very small piece of the very  
4 large puzzle. I mean, one has to look at the  
5 methodology, the question, the study design,  
6 all the variables we've talked about today to  
7 be able to come up to that conclusion rather  
8 than just looking at the relative risk.

9 BY MR. GALLAGHER:

10 Q Okay. Moving on in your report on  
11 Page 22, Section 10.5 "Liver Cancer"?

12 A Yeah.

13 Q So, again, you criticize the Straif  
14 study as lacking the power to -- to examine the  
15 question, right?

16 MR. NIGH: Form objection.

17 THE WITNESS: Right.

18 BY MR. GALLAGHER:

19 Q And then you cite to the Hidajat  
20 study. That's the only other study that you cite  
21 to, right?

22 A That's the only other study that has  
23 looked at liver cancer, you know, in a -- as a  
24 follow-up epidemiological study that my search --  
25 that I could find.

1           Q           All right. In your report on Page 22,  
2     in the Section 10.5, you don't reach any conclusions  
3     about the risk of liver cancer through NDMA  
4     exposure, right?

5                   MR. NIGH: Form objection.

6                   THE WITNESS: Can you repeat the  
7     question?

8     BY MR. GALLAGHER:

9           Q           In your report, in Section 10.5 on  
10    Page 22 of your report --

11          A           Right.

12          Q           You don't reach any conclusions about  
13    the risk of liver cancer through NDMA exposure at  
14    the end of your discussion like you do for the --

15          A           If you mean -- if you mean -- if you  
16    mean I don't have, like, a bolded summary, I -- I  
17    think it was just missed because I do have it for  
18    all the other sections. But, I mean, I do say at  
19    the very last sentence that, "To date, the study by  
20    Hidajat provides the strongest evidence on the risk  
21    of liver cancer."

22          Q           Okay. And you -- you don't have any  
23    other studies that -- you don't -- there are -- as  
24    far as you're aware, there aren't other studies  
25    evaluating the risk of liver cancer from NDMA

1 exposure; is that right?

2 MR. NIGH: Form objection. Do you  
3 mean epi studies or animal studies or all  
4 studies?

5 BY MR. GALLAGHER:

6 Q You're not aware of any other studies  
7 in humans with respect to evaluating risk of  
8 exposure to NDMA and occurrence of liver cancer,  
9 right?

10 MR. NIGH: Form objection.

11 THE WITNESS: I'm not aware of any  
12 human studies that met my inclusion criteria,  
13 which required, again, measurement of NDMA and  
14 demonstration of the effect size, pretty much  
15 everything I have in my inclusion criteria. I  
16 could not find a human study that would fit  
17 those criteria that I could include in my  
18 report.

19 BY MR. GALLAGHER:

20 Q Okay. And so you don't have -- you  
21 don't have any studies that you're relying on that  
22 are evaluating oral exposure to NDMA and risk of  
23 liver cancer, correct?

24 A No.

25 Q Okay. Moving on, Section 10.6 of your



1 report which is looking at bladder cancer?

2 A That's right.

3 MR. GALLAGHER: Can we mark another  
4 Jakszyn article as Exhibit 21? And this is the  
5 Jakszyn article, J-a-k-s-z-y-n, Reference 48  
6 that you're citing to on Page 22?

7 THE WITNESS: Right.

8 (Whereupon, Exhibit 21 was marked for  
9 Identification.)

10 MR. GALLAGHER: So let me know when  
11 that gets pulled up.

12 BY MR. GALLAGHER:

13 Q Do you see it there yet?

14 A I'm here, yeah.

15 Q Okay. So in this article -- or in  
16 this study, this study found no overall association  
17 between exogenous NDMA intake and bladder cancer,  
18 right?

19 A No.

20 Q So the observed relative risk was  
21 1.12, right?

22 A That's right.

23 Q And the confidence interval was 0.88  
24 to 1.4, right?

25 A Yes.

1           Q           So there's no evidence from this study  
2 of any association between NDMA exposure and bladder  
3 cancer, right?

4                   MR. NIGH:   Form objection.

5                   THE WITNESS:  I -- I do present some  
6 of the limitations of the study, but from the  
7 numbers that you cited and that I present, no.

8 BY MR. GALLAGHER:

9           Q           Okay.  And then back to your report,  
10 again, you look at the Straif study, right?

11          A           Yes.

12          Q           You cite to the Straif study, and  
13 there was no evidence or association between  
14 nitrosamines and bladder cancer, right?

15          A           Right.

16          Q           And then you cite to the Hidajat study  
17 in support of your opinions with respect to bladder  
18 cancer, right?

19          A           That's right.

20          Q           And you don't have -- those are the  
21 three studies on which your opinion with respect to  
22 bladder cancer is based, right?

23          A           Yes.

24          Q           And of those three studies, Hidajat  
25 was the only one where there was an observation of a

1 relative risk that -- that reached statistical  
2 significance, correct?

3 A Correct.

4 Q Okay.

5 Moving on. On Page 23 of your report,  
6 you're looking at prostate cancer.

7 A Right.

8 Q Okay. So -- and, again, the first  
9 study you refer to is the Loh study, right?

10 A Right.

11 Q And that study, there was not a  
12 statistically significant -- not a statistically  
13 significant observation for any association of NDMA  
14 exposure with prostate cancer, right?

15 A That's right.

16 Q In fact, the relative risk was 1.01,  
17 right?

18 A Correct.

19 Q The lower bound of the 95 percent  
20 confidence interval is 0.90, and the upper bound was  
21 1.13, right?

22 A Yes.

23 Q Would you consider that confidence  
24 interval precise?

25 A The confidence interval is precise,

1 but that doesn't mean that the -- that the potential  
2 biases in the study that it -- that precluded the  
3 study from showing an effect. So in other words,  
4 it's not a -- it's not a very tight confidence  
5 interval coming from the very well-designed study.

6 So you can't just look at the  
7 precision. You have to put it into context of  
8 the -- what are the potential limitations of this  
9 study that could have led to this nonsignificant  
10 result.

11 Q Okay. You criticize the Loh study  
12 because it doesn't adjust for previous history of  
13 prostate cancer, right?

14 A Well, that's one of the criticisms.  
15 One other criticism is that they also said that  
16 overall in the population that NDMA levels is  
17 relatively low to other populations. They didn't  
18 look at high versus low NDMA, so -- so yeah, so  
19 those are the limitations.

20 Q Okay. The Hidajat study did not  
21 adjust for previous history of prostate cancer,  
22 right?

23 A It did not, but since it showed  
24 again -- because it showed a statistically -- an  
25 increase in risk, that that potential confounding

1 effect of previous history of prostate cancer has to  
2 be quite prevalent in that large population, has to  
3 affect one group more than the other. So, again,  
4 just absence of or not adjusting for a non-measured  
5 confounder doesn't necessarily mean that had it been  
6 included that the results would have been different.

7 So here I'm just mentioning it as one  
8 limitation. But in Hidajat, because they did find  
9 the signal, I think one has to have -- has to put  
10 this into perspective, but in a different Hidajat  
11 versus Loh.

12 Q So you -- if it's -- if it's not  
13 adjusted for and it's an unmeasured confounder, you  
14 don't know what the effect is, right?

15 A We don't know what the effect is, but  
16 we know that the -- that the unmeasured confounder  
17 changes the results when -- when certain conditions  
18 are present. So if let's say, yes, they didn't  
19 adjust for Hidajat for previous history of prostate  
20 cancer, but let's say only .5 percent of the  
21 population of these men had previous history,  
22 because of that low number, adjusting or not  
23 adjusting, because of that low prevalence, would  
24 probably not have changed the results of the study.

25 So, again, unmeasured confounders

1 changed the results of studies if -- you know, based  
2 on a number of other factors, the prevalence, their  
3 strength of association to the outcome and to the  
4 exposure.

5 Q Well, if -- if the -- if the  
6 prevalence of prior history of prostate cancer was  
7 that low in the population, it also wouldn't have  
8 changed the results of the Loh study, right?

9 MR. NIGH: Object to form.

10 THE WITNESS: No, it wouldn't, but  
11 again, I'm not -- I'm kind of mentioning a  
12 number of limitations and potential limitations  
13 for why Loh has that, you know, pardon the pun,  
14 low relative risk, not just unmeasured  
15 confounders.

16 BY MR. GALLAGHER:

17 Q Okay. I understand. But --

18 A Yeah.

19 Q All right. Hidajat has the same  
20 limitation.

21 MR. NIGH: Form objection.

22 BY MR. GALLAGHER:

23 Q Correct?

24 A Hidajat, yes. Hidajat does have the  
25 same limitation, but Hidajat found an increase in

1 risk. And unmeasured -- and the effect of an  
2 unmeasured confounder has to be more profound to  
3 change that result.

4 Here, as we said, the unmeasured  
5 confounder may have been less of an issue because of  
6 the results. However, it is still a limitation that  
7 I thought I should include because, again, we don't  
8 really know, you know, have all the numbers from  
9 this study. We don't know, was it collected or not,  
10 or how it would have changed the results.

11 Q Sure. And you agree that we should  
12 acknowledge the limitations of studies regardless of  
13 if the result was there was an association or not an  
14 association?

15 MR. NIGH: Form objection.

16 THE WITNESS: Yes. But I mean,  
17 limitations have -- I don't -- I don't think we  
18 can paint all limitations with the same brush.  
19 There are some limitations that would not be  
20 that detrimental. There are limitations that  
21 would be.

22 So generally speaking, your -- I agree  
23 with your statement, but at the same time, I  
24 think there could be caveats and nuances on  
25 that statement.

1 Q Okay.

2 THE WITNESS: Can we have a ten-minute  
3 break and come back at 4?

4 MR. GALLAGHER: Sure.

5 THE VIDEOGRAPHER: The time is now  
6 3:50. This ends Media Unit Number 5. We're  
7 going off the record.

8 (Whereupon, a short break was taken.)

9 THE VIDEOGRAPHER: The time is now  
10 4:01. This begins Media Unit Number 6. We're  
11 back on the record.

12 BY MR. GALLAGHER:

13 Q Welcome back, Dr. Etminan.

14 A Thank you.

15 Q Looking again at your report on  
16 Page 23.

17 A Okay.

18 Q And I'm gonna -- you'll be happy to  
19 know I'm going to move ahead to the next section,  
20 10.8: "Blood Cancers."

21 A Okay.

22 Q So you cite a study by Richardson,  
23 right?

24 A Yes.

25 Q And Richardson is --



1 MR. GALLAGHER: Well, why don't we go  
2 ahead and mark it as the next exhibit. Are we  
3 up to 23 now?

4 (Whereupon, Exhibit 22 was marked for  
5 Identification.)

6 MR. GALLAGHER: Okay. This is going  
7 to be -- the Richardson article will be  
8 Exhibit 22.

9 BY MR. GALLAGHER:

10 Q Let me know when that shows up in the  
11 chat, Dr. Etminan.

12 A Okay. So I have it.

13 Q Okay. The title of this article is  
14 "Occupational Risk Factors for Non-Hodgkin's  
15 Lymphoma: A Population Based Case Control Study in  
16 Northern Germany," right?

17 A That's right.

18 Q So this is an occupational study,  
19 right?

20 A Right.

21 Q And the -- you looked at this study  
22 and the odds ratio for exposure to nitrites,  
23 nitrates or nitrosamine, all three combined in terms  
24 of the risk factor for lymphoma, right?

25 A Yes.

1 Q In this study, they didn't -- in this  
2 study, they didn't even try to separate out NDMA  
3 separately, right?

4 A I don't know if they couldn't or  
5 didn't try. It wasn't separated.

6 Q Okay. But regardless of if they  
7 couldn't or didn't try or tried and it didn't work,  
8 the data that you're relying on is looking at  
9 exposure of -- exposure to nitrites, nitrates and  
10 nitrosamine all together, right?

11 MR. NIGH: Form objection.

12 THE WITNESS: Right.

13 BY MR. GALLAGHER:

14 Q And so you're not going to be able to  
15 separate out the specific impact of -- from this  
16 study, specific impact for NDMA risk for lymphoma,  
17 right?

18 A No, not specifically for NDMA.

19 Q You then look at the Straif study --  
20 or you cite to the Straif study again. And  
21 you're -- this is back in your report on Page 23?

22 A Uh-huh.

23 Q Right?

24 A Yes.

25 Q And -- and you have the same criticism

1 for Straif, that it was underpowered as you have  
2 for -- for other of the cancers, right?

3 A Yes.

4 Q But regardless, Straif does not  
5 provide evidence for an association of exposure to  
6 NDMA and occurrence of blood cancers, right?

7 A Let me just look at Straif again  
8 before I -- I mean, they had -- they had a small  
9 number of cases. They looked at nitrosamines. I  
10 mean, similar in structure, but not NDMA, per se.  
11 And they -- I mean, there was an increase in risk  
12 with lymphoma but not significant because of small  
13 number of cases.

14 Q Next -- and then you cite again to the  
15 Hidajat study, right?

16 A Right.

17 Q And you're looking at the data from  
18 Hidajat for lymphoma, leukemia and multiple myeloma,  
19 right?

20 A Right.

21 Q So really, Hidajat is the only study  
22 that you're citing to in support of your opinion  
23 with respect to exposure to NDMA and any association  
24 with blood cancers, right?

25 A Right.

1 MR. NIGH: Form objection.

2 BY MR. GALLAGHER:

3 Q Moving on to Section 10.9 of your  
4 report on Page 24, which is "Lung Cancer"?

5 A Okay.

6 Q So, for lung cancer, you cite to a  
7 De Stefani article?

8 A Uh-huh.

9 Q Right?

10 A Is there an exhibit?

11 Q It's a 2009 article that you cited to.  
12 That's what Citation Number 44 is.

13 A Right. Are you going to upload it, or  
14 am I just going to look at it here?

15 MR. GALLAGHER: Can we go ahead and  
16 mark that.

17 (Whereupon, Exhibit 23 was marked for  
18 Identification.)

19 MR. GALLAGHER: So that's Exhibit 23,  
20 and I'm also going to mark now as Exhibit 24 a  
21 De Stefani article from 1998.

22 (Whereupon, Exhibit 24 was marked for  
23 Identification.)

24 BY MR. GALLAGHER:

25 Q Do you have Exhibit 23 in front of

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1 you?

2 A Yes.

3 Q Okay. This -- this study was looking  
4 at meat intake and risk of lung cancer; is that  
5 right?

6 A I just want to note, make sure that  
7 this is the one that I cite.

8 Q Okay. We had some confusion there to,  
9 so that's why I'm going to pull up the other one.

10 A The meat intake one, I don't think it  
11 provided NDMA levels. I don't think that I used  
12 that. I think I used the other one.

13 Q Okay. If you look in your report,  
14 looking at Page 24, under "Lung Cancer," you say, "A  
15 study by De Stefani examined the risk of lung cancer  
16 among subjects exposed to different levels of NDMA  
17 through diet."

18 Do you see that, right?

19 A Right. I think that should be another  
20 De Stefani. It probably got mixed up.

21 Q Okay. But if we go to --

22 A If we go to the '96 article.

23 Q Okay. But if we go to Page 38 of --  
24 of your report, listing the references?

25 A Uh-huh.

1           Q           The -- Reference 44 you're citing to  
2           this article "Meat Intake, Meat Mutagens and Risk of  
3           Lung Cancer in Uruguayan Men."

4                   THE COURT REPORTER: I'm sorry. I'm  
5           sorry. Excuse me.

6                   MR. GALLAGHER: Do you need me to  
7           repeat the question with it?

8                   THE COURT REPORTER: No.

9                   MR. GALLAGHER: Do you need  
10          Dr. Etminan to repeat his answer?

11                   THE COURT REPORTER: Yes.

12          BY MR. GALLAGHER:

13          Q           I'll repeat the question.

14                   So Dr. Etminan, here in your report,  
15          Reference 44 is this De Stefani article from 2009  
16          titled, "Meat Intake, Meat Mutagens and Risk of Lung  
17          Cancer in Uruguayan Men," right?

18          A           Right. And I believe that that should  
19          actually be another -- should be replaced by another  
20          De Stefani. It got mixed up, some so the De Stefani  
21          data that I included is from the De Stefani '96 in  
22          "Cancer Epidemiology" --

23                   THE COURT REPORTER: What markers?

24                   THE WITNESS: "Cancer Epidemiology  
25          Biomarkers and Prevention."

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1 THE COURT REPORTER: Thank you.

2 BY MR. GALLAGHER:

3 Q But you agree with me that this 2009  
4 article does not separately evaluate levels of NDMA,  
5 right?

6 A Right.

7 Q Okay.

8 MR. GALLAGHER: We'll mark as  
9 Exhibit 24 a 1996 De Stefani article. Let me  
10 know when that shows up in your chat.

11 THE WITNESS: Sorry. That should be  
12 De Stefani 2000 -- is it -- exhibit which  
13 number?

14 BY MR. GALLAGHER:

15 Q Exhibit 24. It should be coming  
16 shortly.

17 A Right. 24, okay.

18 Q Have you got it?

19 A Yes.

20 Q Okay. So is this -- this is the  
21 article that you meant to refer to?

22 A Yes.

23 Q That's in Reference 44 from your  
24 report?

25 A Yes.

1 Q Okay. And the title of this -- this  
2 is an older article than Exhibit 23 that we were  
3 just looking at, right?

4 A That's right.

5 Q And this is entitled, "Dietary  
6 Nitrosodimethylamine and the Risk of Lung Cancer: A  
7 Case Control Study from Uruguay," right?

8 A That's right.

9 Q Okay. So this -- this was a dietary  
10 study, right?

11 A Yes.

12 Q And this is subject to the same  
13 limitations of the other dietary studies that we've  
14 talked about in terms of -- errors in filling out  
15 the dietary questionnaire would be one, right?

16 A Well, again, dietary questionnaires,  
17 usually, the error is differential --  
18 non-differential -- pardon me, non-differential.  
19 Here they do show a risk, but it is a dietary  
20 questionnaire study. So generally speaking, it  
21 could have limitations, but I don't -- I mean, I  
22 can't even think of a specific reason why the -- a  
23 specific reason as to why they put limitations in  
24 terms of the questionnaire would, you know, would  
25 affect the results. But generally speaking, all



1 dietary studies could have --

2 THE COURT REPORTER: Could have what?

3 THE WITNESS: Limitations.

4 THE COURT REPORTER: Thank you.

5 BY MR. GALLAGHER:

6 Q Okay. And this is a case control  
7 study, correct?

8 A Yeah. Yeah.

9 Q Would you consider this a  
10 retrospective study?

11 A Yes.

12 Q Is there a potential for recall bias  
13 for the dietary questionnaire?

14 A There could be. In all dietary  
15 studies that's a possibility.

16 Q Okay. And is a part of -- a part of  
17 what leads to that recall bias could be that the  
18 cases for those with lung cancer feel more invested  
19 in identifying what the -- what led to their  
20 diagnosis, whereas the controls are not in the -- in  
21 the same type of a situation, right?

22 THE COURT REPORTER: I'm sorry. What  
23 was the objection?

24 MR. NIGH: Form objection.

25 THE COURT REPORTER: And was there an

1 answer?

2 THE WITNESS: I said that it's  
3 possible.

4 BY MR. GALLAGHER:

5 Q Okay. Moving on in your report, you  
6 next cite to a study by Goodman?

7 A Yes.

8 Q One more thing. Back in your report,  
9 when you're discussing the De Stefani article --

10 MR. GALLAGHER: If we can highlight  
11 that section. Yup.

12 BY MR. GALLAGHER:

13 Q And you talk about, "The study  
14 identified 320 cases of lung cancer and matched them  
15 to 320 controls," right?

16 A Yeah.

17 Q And -- and then you say, "After  
18 adjusting for important confounding variables,  
19 including pack-years of smoking and history of lung  
20 cancer," and you go on to talk about the data.

21 A Uh-huh.

22 Q So you agree that smoking and past  
23 history of cancer are important confounding  
24 variables, right?

25 A Yes. And if you have the data, if

1     you -- have the data available, it should be  
2     adjusted for. I think what we talked about, in a  
3     different sort of context, today is that lack of an  
4     unmeasured confounder doesn't always mean that the  
5     results would be biased. But if you have a  
6     confounder that is important and it's been  
7     collected, then by all means, it should be --

8                     THE COURT REPORTER: It should be  
9     what?

10                    THE WITNESS: Controlled for.

11     BY MR. GALLAGHER:

12             Q             And so for studies that don't control  
13     for these important confounding variables, that is a  
14     limitation of those studies, right?

15             A             It is a limitation, but again, we  
16     have -- we have sort of techniques, too, that we can  
17     use to simulate the data and see how it affects --  
18     it would affect the results. And it is a  
19     limitation, but it does not necessarily mean that  
20     the study should not be believed in. Because, as  
21     I -- as I mentioned a number of times, a lack of an  
22     unmeasured confounder doesn't always lead to, you  
23     know, biased results. It depends on a number of  
24     criteria and situations on the confounding.

25             Q             Right. But you don't know if -- if

1 any one given confounding variable -- actually,  
2 unmeasured confounding variable, actually did bias  
3 the results, right?

4 MR. NIGH: Form objection.

5 THE WITNESS: Exactly and precisely,  
6 no, unless you have the data.

7 BY MR. GALLAGHER:

8 Q Okay. And when you have multiple  
9 unmeasured confounding variables, that just  
10 complicates it even more in terms of whether one or  
11 more of those multiple unmeasured confounding  
12 variables actually bias the results, right?

13 MR. NIGH: Form objection.

14 THE WITNESS: If -- if those -- a lot  
15 of times, these variables that, you know, are  
16 mentioned as confounders are not true  
17 confounders. They are risk factors as we  
18 talked about it. So in -- in a situation of  
19 risk factors, I -- I don't think again, lack of  
20 measuring for a risk factor only affects the  
21 precision around the effect size. It --  
22 usually minimally, doesn't change the  
23 direction. So to answer your question, yes,  
24 but a lot of times, these are not really  
25 unmeasured confounders. They are just risk

1 factors. Yeah.

2 BY MR. GALLAGHER:

3 Q Okay. Moving on in your report, now  
4 you cite to a study by Goodman?

5 A Yes.

6 MR. GALLAGHER: And let's go ahead and  
7 mark this. This is going to be Exhibit 25.  
8 Let me know when you have it.

9 (Whereupon, Exhibit 25 was marked for  
10 Identification.)

11 THE WITNESS: I have it.

12 BY MR. GALLAGHER:

13 Q So this article, Exhibit 25, is  
14 titled, "High Fat Foods and the Risk of Lung  
15 Cancer," right?

16 A Yes.

17 Q So this study is focusing on the  
18 effect of dietary cholesterol and dietary fat on  
19 lung cancer risk, right?

20 THE COURT REPORTER: And dietary what?

21 MR. GALLAGHER: Dietary fat.

22 THE WITNESS: Okay.

23 BY MR. GALLAGHER:

24 Q And this was a diet history survey,  
25 right?

1 A Yes.

2 Q And, in fact, in almost -- this is a  
3 diet history survey, and do you understand that --  
4 so in terms of a diet history survey, that's  
5 different from a food frequency questionnaire; is  
6 that right?

7 MR. NIGH: Form objection.

8 THE WITNESS: Let me just -- can I  
9 just read it for a few minutes?

10 BY MR. GALLAGHER:

11 Q Sure.

12 MR. GALLAGHER: Can we go off the  
13 record for a minute while he -- to give him  
14 time to review?

15 THE VIDEOGRAPHER: The time is now  
16 4:25. We're going off the record.

17 (Whereupon, a short break was taken.)

18 THE VIDEOGRAPHER: The time is now  
19 4:27. We're back on the record.

20 BY MR. GALLAGHER:

21 Q Okay. So this -- this study uses diet  
22 history survey, right?

23 A Yes.

24 Q Okay. And, in fact, in -- in many  
25 instances, the subject of the study wasn't

1 available, and so they actually used -- did an  
2 interview with a surrogate in order to collect the  
3 historic information on diet history, right?  
4 Maybe -- go ahead.

5 A Yes, I mean, in a lot of dietary  
6 studies, especially when the patients are elderly,  
7 it's usually a family member who helps to complete  
8 the questionnaire. So -- I don't think this is that  
9 much of a difference in, sort of, a step involving  
10 the survey versus other dietary questionnaires that  
11 we see.

12 Q Okay. If we turn to Page 289 of the  
13 Goodman article?

14 A Yes.

15 Q And here, this is the section  
16 describing subjects and methods. On the left-hand  
17 side, the paragraph second from the bottom starts,  
18 "In some instances." And this is describing --

19 A Yeah.

20 Q -- why in some circumstances they  
21 obtained surrogate interviews from the spouse or  
22 next of kin, right?

23 A Yeah.

24 Q And for this study, surrogate  
25 interviews were conducted for 29 percent of the

1 cases, but only 7 percent of the controls, right?

2 A Right.

3 Q So there's an unequal -- there's an  
4 unequal distribution of surrogate interviews for the  
5 cases versus for the controls, right?

6 A Right. But you're -- I think you're  
7 automatically assuming that the unequal distribution  
8 leads to, say, again, measurement error on the part  
9 of the cases. And we -- we don't know if that's the  
10 case. I mean, it could, in fact, because it's --

11 Q Sure.

12 A -- it could actually improve accuracy.  
13 We don't know. All we know is that there is a  
14 difference in percentage of those who used the  
15 surrogate versus those who didn't.

16 Q Okay. So we have already talked about  
17 one of the -- and it's just an inherent limitation  
18 of dietary studies, is the potential for  
19 inaccurately reporting in terms of foods that the  
20 subject does eat, the food frequency.

21 A Generally speaking, yes --

22 MR. NIGH: Hold on. Form objection.

23 Form objection.

24 Go ahead. You can answer.

25 THE WITNESS: Generally speaking, I



1 think it's -- we talked about this already.

2 BY MR. GALLAGHER:

3 Q Okay. And there certainly is a  
4 possibility that a surrogate will have a different  
5 level of accuracy than the subject themselves in  
6 recalling foods that the subject has -- has  
7 typically eaten, correct?

8 MR. NIGH: Form objection.

9 THE WITNESS: It's -- it's possible.

10 BY MR. GALLAGHER:

11 Q And especially where the -- the  
12 percentage of surrogate interviews for the cases is  
13 different from the percentage of surrogate  
14 interviews for the controls. Any difference in  
15 accuracy of the surrogates and the actual subjects,  
16 both see the data, right?

17 MR. NIGH: Form objection.

18 THE WITNESS: Again, if you're  
19 assuming that there are measurement errors with  
20 the cases versus the controls. If that would  
21 be the case, then, yes.

22 BY MR. GALLAGHER:

23 Q Okay. And just to be clear, I'm not  
24 just asking about differences in recall of cases  
25 versus controls.

1 I'm asking about, there can be  
2 differences in -- in recall of foods that were  
3 typical in a person's diet if the person answering  
4 the question is the subject themselves versus if the  
5 person answering the questions is a surrogate for  
6 the subject, right?

7 A Yes.

8 Q Back to your report on Page 24, the  
9 second paragraph of "Lung Cancer," that is referring  
10 to the Goodman study.

11 A Uh-huh.

12 Q So after discussing the odds ratio,  
13 you say, "One limitation of Goodman is that it is  
14 unclear how duration of exposure to nitrosamines was  
15 assessed."

16 Do you see that?

17 A Yes.

18 Q You agree with me that duration of  
19 exposure to nitrosamine is a factor that has to be  
20 considered in terms of evaluating them if there's  
21 any potential risk factor, right?

22 A Yes. And, again, that's why I'm  
23 also -- in forming my opinion, I'm also relying on  
24 the Hidajat study, which measured NDMA exposure  
25 through inhalation, which would have a direct effect

1 in this specific -- for this specific cancer on the  
2 lung.

3 Q Okay. And then in your report you  
4 next cite to the Loh study, which we have looked at  
5 and discussed previously. The Loh study reports a  
6 relative risk of 1.05, a 95 percent confidence  
7 interval of 0.88 to 1.24, correct?

8 A Yes.

9 Q So you would agree with me that the  
10 Loh study does not provide evidence of an  
11 association between NDMA exposure and risk of lung  
12 cancer, right?

13 A Correct.

14 Q Okay. Going back to the odds ratios  
15 for -- from the Goodman study, for the first one  
16 which is intake of NDMA in men, the confidence  
17 interval is 1.7 to 6.2, right?

18 A Yes.

19 Q Would you consider that confidence  
20 interval to be imprecise?

21 MR. NIGH: Form objection.

22 THE WITNESS: No. Imprecise, we  
23 usually mean imprecise when it crosses 1 and  
24 goes beyond 1, and -- and -- so that the lower  
25 bound goes from, say, minus 1 -- or minus 1,

1 and the upper bound goes to greater than 1.

2 That's what they call imprecise.

3 If it's -- if it's some sort of skew  
4 to the right from 1.1 or higher, as it is in  
5 this case, we wouldn't say that's imprecise.

6 BY MR. GALLAGHER:

7 Q Okay. Well, if there's no  
8 association, you would expect the confidence  
9 interval to go below 1 and above 1, correct?

10 A I'm sorry. Can you clarify the  
11 question?

12 Q If there's no association between the  
13 exposure and the outcome, you would expect the  
14 confidence interval, the lower bound to be below 1  
15 and the upper bound to be above 1, correct?

16 A Well, that's -- again, I think we  
17 talked about this. So that would be an  
18 inconclusive. I wouldn't say no association. If  
19 the effect size is greater than 1, but the  
20 confidence intervals are as wide as you just  
21 mentioned, that would be an inconclusive sort of a  
22 result rather than no association.

23 Q Okay. I guess, I didn't say the  
24 confidence intervals were wide. I just said if  
25 there's no association, you would expect the lower

1 bound of the confidence interval to be below 1 and  
2 the upper bound of the confidence interval to be  
3 above 1, right?

4 A Yes. So, again, what you're  
5 portraying the confidence interval that's -- that  
6 crosses 1. So it goes either way, and, again, that  
7 fits the -- again, we don't have specific numbers  
8 here. But that usually fits the definition of  
9 imprecision or uncertain results, not necessarily  
10 negative results, uncertain results. Or  
11 inconclusive results.

12 Q Okay. If you had a study that was  
13 extremely well-powered, and you -- you actually did  
14 observe from the data a relative risk of 1.0, and  
15 the confidence interval was 0.98 to 1.02, are you  
16 telling me that you would consider that confidence  
17 interval to be imprecise?

18 MR. NIGH: Form objection.

19 THE WITNESS: No. But, again, in your  
20 example, you didn't -- you didn't specify  
21 numbers with the numbers that you're -- you're  
22 giving me now, which -- which seem to be very  
23 tight. And, again, if -- if this is a  
24 non-biased study, a perfectly designed study,  
25 then that would be a no association.

1 BY MR. GALLAGHER:

2 Q Okay. And so this discussion about  
3 imprecise confidence intervals are when it's -- the  
4 lower bound is below 1 and the upper bound is above  
5 1, that's not actually a measured determination of  
6 whether the confidence interval is precise or not,  
7 right?

8 A Again, it -- it depends on the -- what  
9 the confidence interval is -- what the effect size  
10 is, and what the confidence interval is around that  
11 effect size. The example that you gave me fits your  
12 description, but if you have situations where you  
13 have, say, a relative risk of 4 and a very wide  
14 confidence interval, that does not -- that does not  
15 mean that there is no association. That means that  
16 that's an inconclusive study. So, again, I can't --  
17 at least, I can't come up with a cookie-cutter  
18 definition. It depends on what the effect size is,  
19 and what the confidence interval around the effect  
20 size is.

21 Q Okay. You can't come up with a  
22 cookie-cutter definition, but are there -- are there  
23 some sort of standards around what you're  
24 considering to be an imprecise confidence interval  
25 versus a precise confidence interval?

1 A Yes, so again --

2 MR. NIGH: Form objection.

3 Go ahead. You can answer.

4 THE WITNESS: If the relative risk of  
5 a study is 4 and the 95 confidence interval is  
6 from .3 to 15, that would be an inconclusive  
7 study. If the relative risk of the study is 4  
8 and the -- and the lower bound starts from 1.8  
9 to 6, that is not an imprecise study. That  
10 is -- that confidence interval, we call it a  
11 relatively tight confidence interval.

12 BY MR. GALLAGHER:

13 Q Okay. And then back to your report on  
14 Page 24, the next paragraph, you cite to the Hidajat  
15 study again, right?

16 A Yes.

17 Q And you cite to that, where the hazard  
18 ratio reported by Hidajat for exposure and NDMA  
19 having a potential association of lung cancer with  
20 the hazard ratio being 1.70, right?

21 A Yes.

22 Q And as we have discussed, the Hidajat  
23 study is an occupational study in the rubber  
24 industry in the UK where the exposure to NDMA was  
25 primarily through inhalation, not oral, right?

1 A Yes.

2 Q And as I think you just mentioned,  
3 there's perhaps some plausibility to why inhalation  
4 of something may have an impact that the lung --  
5 that oral ingestion would not, right?

6 A Can you repeat that last question,  
7 please?

8 Q Sure.

9 I think you had referenced in one of  
10 your earlier answers that you can understand why  
11 inhalation of a substance could -- could have some  
12 sort of an impact on the lungs, right?

13 A Yeah. I mean, inhaling a carcinogen  
14 would have probably more of a -- would -- would  
15 have -- would be able to impose more of its  
16 carcinogenic effect because it's directly affecting  
17 that organ. But eventually, it will be -- it will  
18 be absorbed systemically over time. It's just that  
19 the first organ its seeing is the lungs because it's  
20 going through inhalation. So it may affect the  
21 organ -- the lungs more, but over time, it will be  
22 systemically absorbed and affect potentially other  
23 parts of the body.

24 Q Okay. And as we talked about, workers  
25 in rubber factories are not just inhaling NDMA.



1 They're inhaling all sorts of things, including  
2 rubber dust, rubber fumes, benzine. There's all  
3 sorts of things that are --

4 MR. NIGH: Hold on. I'd like to  
5 object here. This is about the 20th plus time  
6 that I've heard this same question, you know.  
7 I think there was an instruction not to be  
8 cumulative. We have been patient. We have let  
9 the cumulative questions come on multiple  
10 topics, but this is the point as to which it's  
11 becoming very much overly cumulative. It's the  
12 same question over and over on the same topic.  
13 And I could come up with probably 20 examples  
14 right now of the same question being asked.

15 You know, at this point, I -- you  
16 know, I would caution the counsel that  
17 they're -- I think that counsel may be thinking  
18 they have 10 hours of record time. I do not  
19 believe that's the case. I think that there  
20 were strings that were attached and things that  
21 were said that -- you know, in terms of  
22 seven hours and when the exception may apply.  
23 And, frankly, I don't think that that exception  
24 is applied here.

25 So, again, I would object. This has

1           become completely overly cumulative. And I  
2           would rest on the federal rules of seven hours  
3           saying that none of the exceptions have been  
4           met for the judge's ruling on 10 hours in this  
5           case.

6                       You can answer.

7                       THE WITNESS: Sorry. I forgot what  
8           the question was.

9                       MR. GALLAGHER: You know, I think the  
10          judge was -- was very clear in his ruling that  
11          we had 10 hours, and was equally as clear  
12          during the Hecht deposition and unhappy when he  
13          was bothered in the middle of dinner and the  
14          deposition had not -- was not anywhere close  
15          to -- to 10 hours. So moving on.

16       BY MR. GALLAGHER:

17               Q           Dr. Etminan, on Section 11 in your  
18          expert report?

19               A           Yes.

20               Q           This is addressing epidemiologic  
21          studies of valsartan-containing NDMA and cancer,  
22          right?

23               A           Yes.

24               Q           In these studies, they are actually  
25          addressing the exposure -- well, let me step back

1 for a minute.

2 MR. GALLAGHER: Let's mark as  
3 Exhibit 26, the Pottegard study, and as  
4 Exhibit 27 the Gomm, G-o-m-m, study.

5 (Whereupon, Exhibit 26 was marked for  
6 Identification.)

7 (Whereupon, Exhibit 27 was marked for  
8 Identification.)

9 BY MR. GALLAGHER:

10 Q Let me know when those two exhibits  
11 show up, Exhibit 26 and 27.

12 THE WITNESS: Sorry. I got  
13 disconnected and got reconnected. There is  
14 nothing in the -- okay, I see it now.

15 BY MR. GALLAGHER:

16 Q Okay. You have Exhibit 26 as the  
17 Pottegard study, right?

18 A Yeah.

19 Q And Exhibit 27 is that there also, the  
20 Gomm study?

21 A I just got 26 for now. Yes.

22 Q So both of these studies are  
23 evaluating the exposure that's actually at issue in  
24 this litigation, right, which is exposure to  
25 valsartan that contains some small amount of NDMA's

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1 of impurity, right?

2 A They're not -- I disagree. They're  
3 not -- they're not quantifying the NDMA valsartan.  
4 They are only looking at valsartan tablets and  
5 doses.

6 Q The exposure that they're evaluating  
7 is -- so the title of the Pottegard study is "Use of  
8 N-nitrosodimethylamine (NDMA) Contaminated Valsartan  
9 Products and Risk of Cancer: Danish Nationwide  
10 Cohort Study," right?

11 A That -- that is the title, but if you  
12 read the study -- the exposure that we're here today  
13 to talk about is NDMA and its risk of cancer, and so  
14 the study should address the amount of NDMA in  
15 valsartan and its risk with cancer. What it does,  
16 though, is look at valsartan tablets that have some  
17 NDMA in it, in them, we don't know how much.

18 And with respect to Pottegard, we --  
19 we are not even sure if the -- the control valsartan  
20 group didn't have NDMA in those formulations.

21 So there is definitely measurement  
22 error going on in quantifying -- appropriately  
23 quantifying NDMA in valsartan along with other  
24 limitations.

25 Q Why do you say that there's definitely

1 measurement error?

2 A Because NDMA levels vary in different  
3 batches or different types of valsartan. But there  
4 are many different generic valsartan products, and  
5 they may have different levels of NDMA in them. So  
6 higher levels may put somebody at a higher risk of  
7 cancer, and this study did not look at that, which I  
8 think is an important distinct that should be looked  
9 at.

10 And also because the study was done  
11 early on, it turns out that some of the control  
12 group, which they -- they thought did not have NDMA  
13 in them probably did have NDMA in them as well. So  
14 there is again an error in measurement between the  
15 two groups. So that is -- that is the limitation of  
16 the, you know, measurement error portion of this  
17 study.

18 Q Okay. So am I understanding right,  
19 they would have to know the amount of NDMA that each  
20 of the subjects was actually exposed to to evaluate  
21 whether there actually is a risk of these cancers,  
22 from that literature?

23 A They would have to -- they would have  
24 to categorize -- have had to categorize the  
25 different levels of -- hello?

1 MR. GALLAGHER: I can hear you. Does  
2 somebody else need to mute, maybe?

3 THE WITNESS: Yeah, there's an echo.

4 They should have -- maybe they  
5 couldn't, but the -- the right thing to do is  
6 to categorize different NDMA levels in these  
7 valsartan tablets and categorize them to say:  
8 High, medium and low dose. And then follow  
9 patients for more than the amount of time, I  
10 think it's three years, I believe, that they  
11 did, to make sure that they are at risk of  
12 developing cancer.

13 And then also make sure that the  
14 control group does not have any NDMA in  
15 those -- in those batches. And they can also  
16 make sure there's no switching going on,  
17 because, again, patients take these drugs from  
18 their pharmacy. And they don't really specify  
19 which generic formulation they get. So there  
20 could be switching between patients, and they  
21 could be switching between the doses of NDMA  
22 over time. So all of those limitations I think  
23 probably led to the negative results.

24 BY MR. GALLAGHER:

25 Q Okay. You do agree with me that the

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1 Pottegard study reports a negative result in terms  
2 of any association between exposure to NDMA as an  
3 impurity in valsartan and --

4 A Well, again, negative results with the  
5 caveat of a number of limitations.

6 Q Okay. And among those -- among those  
7 limitations that you've identified is the people  
8 conducting the study would need to somehow quantify  
9 the amount of NDMA to which the subjects were  
10 actually exposed in order to evaluate that potential  
11 association of exposure to NDMA as an impurity of  
12 valsartan with cancer?

13 A Right. I make sure that those --  
14 those patients are taking these higher levels of  
15 NDMA for at least a specific period of time to allow  
16 the cancer process to sort of form and be diagnosed.

17 You know, if somebody takes the drug  
18 for three months and then leaves the study, that --  
19 that is not a good follow up for this study. You  
20 need long follow up. You need minimal switching.  
21 You need specific NDMA dosing information for the  
22 subjects, and you need to make sure that the control  
23 group are all clean valsartan users, and there's no  
24 NDMA in them as well.

25 Q Okay. Moving on to the Gomm study, do

1 you have that now, Exhibit 27, I believe?

2 A Yes.

3 Q And you're addressing the Gomm study  
4 on Page 26 of your report. From your perspective,  
5 does the Gomm study, you know, essentially have,  
6 from your perspective, the same limitations as we  
7 just discussed for the Pottegard study?

8 A Yes, I would again --

9 MR. NIGH: Hold on. Hold on. Let me  
10 object. Form objection.

11 You can answer, Dr. Etminan.

12 THE WITNESS: Yes. Again, just like  
13 Pottegard, there's no specification of the NDMA  
14 content in the valsartan users, and I think  
15 they actually say possible or probable  
16 contamination. So there's a feeling of  
17 uncertainty as to, you know, whether, say, for  
18 example, the control group had any NDMA or did  
19 not have any NDMA. There's no discussion of  
20 what if people switch between the, you know,  
21 different doses which could have had different  
22 NDMA levels.

23 And then there is the problem of only  
24 a three-year follow up, which for a cancer is  
25 quite inadequate. And there's also some



1 evidence of selection bias as well.

2 BY MR. GALLAGHER:

3 Q Okay. And with respect to -- just  
4 discussing -- discussing the limitation you have  
5 identified of -- of time to follow up, you  
6 understand that these -- these products were on the  
7 market only relatively recently. So between  
8 approximately 2014 and 2018, there's -- there's not,  
9 at the moment, an opportunity for any longer follow  
10 up, right?

11 MR. NIGH: Form objection.

12 THE WITNESS: Yes. I mean, that is  
13 the problem. But that doesn't take away from  
14 the fact that -- I mean, if you can't do this  
15 study, you shouldn't do it. You should wait  
16 until you have adequate follow up. You cannot  
17 do sort of a -- you cannot disregard an  
18 important part of this study design, which is  
19 adequate follow up, because there just simply  
20 isn't enough data. I mean, they could have  
21 waited until more data is accumulated before  
22 they actually did this study.

23 BY MR. GALLAGHER:

24 Q It's not that they necessarily  
25 shouldn't do the study, but it's just acknowledging

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1 that there's no other data. There's no longer term  
2 follow up data that's available right now?

3 A Okay.

4 MR. GALLAGHER: I want to be sensitive  
5 to the court reporter. We have been going for  
6 an hour, when she asked that that be how far we  
7 go, so can we -- can we go off the record now?

8 THE VIDEOGRAPHER: The time is now  
9 4:59. We're going off the record. This ends  
10 Media Unit Number 6.

11 (Whereupon, a short break was taken.)

12 (Whereupon, the deposition concluded  
13 at 4:59 p.m.)

DEPOSITION REVIEW  
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4772261

CASE NAME: Valsartan

DATE OF DEPOSITION: August 24, 2021

WITNESS: MAHYAR ETMINAN, Ph.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

\_\_\_\_\_  
Date Mahyar Etminan

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;  
They have listed all of their corrections in the appended Errata Sheet;  
They signed the foregoing Sworn Statement;  
and

Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_\_,

\_\_\_\_\_  
Notary Public

\_\_\_\_\_  
Commission Expiration Date

## DEPOSITION ERRATA SHEET

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MAHYAR ETMINAN

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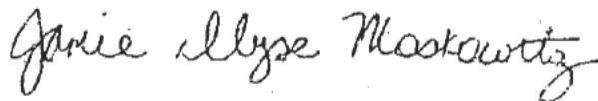
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C E R T I F I C A T E

I, Jamie I. Moskowitz, a Shorthand  
(Stenotype) Reporter and Notary Public, do hereby  
certify that the foregoing Deposition, of the  
witness, MAHYAR ETMINAN, taken at the time and place  
aforesaid, is a true and correct transcription of my  
shorthand notes.

I further certify that I am neither  
counsel for nor related to any party to said action,  
nor in any way interested in the result or outcome  
thereof.

IN WITNESS WHEREOF, I have hereunto set  
my hand this 1st day of September 2021



Jamie Ilyse Moskowitz

License No. XI01658

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.



VERITEXT LEGAL SOLUTIONS  
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